

VOLUME 1 OF 2.



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**Improving The Effectiveness of HIV Prevention:  
A randomised controlled trial of a small group behavioural  
intervention for ‘high-risk’ gay men attending  
genitourinary medicine clinics**

by

**John Chisholm Gray Imrie**

**Volume 1**

Submitted for the degree of

**Doctor of Philosophy**

in

**AIDS and HIV Infection**

Centre for Sexual Health and HIV Research  
Department of Primary and Population Sciences  
Royal Free and University College Medical School  
University College London  
January 2005

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## **Abstract of the thesis**

**Improving the effectiveness of HIV prevention: A randomised controlled trial of a small group behavioural intervention for ‘high-risk’ gay men attending genitourinary medicine clinics.**

Gay men are one group that is seriously affected by HIV in the UK. Prevention interventions have been widely implemented, but few have been rigorously evaluated for their effectiveness. This thesis describes the first randomised controlled trial (RCT) of a small group behavioural intervention for ‘high-risk’ gay men attending genitourinary medicine (GUM) clinics to use incident sexually transmitted infections (STI) as the primary endpoint and examines its impact on local prevention policy and practice.

A total of 343 gay men GUM clinic attenders were randomised to either standard management (brief session with a counsellor) or standard management plus a brief small group behavioural intervention delivered by trained co-facilitators. Follow up was by questionnaire at 6 and 12 months for self-reported behavioural outcomes and record review of the clinic databases for new STI diagnoses and treatment.

The participation rate was 72.3%. Of those randomised to the intervention, 70.9% attended. Questionnaire follow up was 80.5% at 6 months and 71.1% at 12 months. In total, 89.8% of men returned one or both follow up questionnaires or had an STI screen (with results available) during the follow up. At baseline, 36.6% of intervention participants vs. 30.1% of controls

reported unprotected anal intercourse (UAI) in the last month. At 12 months, these proportions were 27.2% and 31.5% respectively (adjusted  $p$ -value = 0.32). However, 30.8% of intervention participants vs. 20.8% of controls had at least one STI diagnosed at the clinic during follow up (Odds Ratio = 1.692; 95% Confidence Interval: 1.033–2.772). Although intervention participants were slightly more likely to have an STI screen during the follow up period (52.9% vs. 48.2%), they were also more likely to screen positive for a new STI (Adjusted odds ratio = 1.841; 95% Confidence Interval 0.996–3.40).

Process evaluation and secondary analysis identified 3 possible explanations for these unanticipated results. These were: 1) inappropriate choice and use of behavioural change theories in determining the intervention content; 2) a mis-match between intervention facilitators' and participants' expectations and perceptions of the intervention; and 3) an unintended intervention effect of the trial's retention and follow up procedures.

The study concluded that the intervention did not reduce risk of acquiring an STI and demonstrated that even carefully conceived interventions should be rigorously evaluated.

The trial results did not result in immediate changes in clinic practice or local HIV prevention policy. The thesis concludes that provision of rigorous research evidence alone cannot bring about changes in either HIV prevention policy or prevention practice.

‘... soldiers who have been bloodied are soldiers forever. ...they will never allow themselves to heal completely, is their way of expressing their love for friends who have perished. ... they have become what they have become to keep the fallen alive.’

Mark Helprin, *A Soldier of the Great War*

## ACKNOWLEDGEMENTS

Over the years taken to complete this project, many people have helped me and I owe all of them A debt of gratitude.

Dr Judith Stephenson, my supervisor, supported my decision to study for a PhD. She encouraged me to use the example of the BIG Project, to further my interest in behavioural intervention research and facilitated the study leave that enabled me to complete this dissertation. I wish to thank her for this and for her helpful comments on the various drafts of the thesis. I am grateful to Professor Graham Scambler, my second supervisor, for providing useful comments on an earlier draft.

Friends and colleagues, past and present, in the Centre for Sexual Health and HIV Research deserve a special expression of thanks. Their professionalism, friendship, support and understanding ensured I remained focused on the ultimate goal. Thank you all.

Two friends, Donald McDowall-Wilson and Ian Macpherson, have always been there to support me. In particular, Donald's determination and encouragement to finish has helped no-end and kept me motivated and focused. A simple thank you is not adequate acknowledgement of their help.

Above all, thank you to my partner, Paul Bean. Throughout he has shown complete faith in me. His support has been solid and steadfast; and his patience and love never failed to comfort and uplift. For you, hopefully '*the longest PhD in history*' is now over.

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## **ABBREVIATIONS**

**Adj OR** – Adjusted odds ratio

**AI** – Anal intercourse

**AIDS** – Acquired immune deficiency syndrome

**BIG Project** – Behavioural Intervention In Gay men Project

**CBT** – Cognitive behavioural theory

**CDC** – Centers for Diseases Control and Prevention, Atlanta, USA

**CDSC** - Communicable Diseases Surveillance Centre, Public Health Laboratory Service

**CI** – Confidence Interval

**DH or DoH** – Department of Health

**GMFA** – Gay Men Fighting AIDS

**GUM** – Genitourinary medicine

**HDA** – Health Development Agency

**HEA** – Health Education Authority

**HIV** – Human immunodeficiency virus

**HPA** – Health Protection Agency

**OR** – Odds ratio

**PE** – Peer educators

**PSE** – Public sex environment

**RCT** – Randomised controlled trial

**RMP** – Regular male partner

**SCIEH** – Scottish Centre for Infection and Environmental Health, Glasgow, Scotland

**SCIS** – Service commissioning information system

**STD** – Sexually transmitted disease

**STI** – Sexually transmitted infections

**UAI** – Unprotected anal intercourse

**UCL** – University College London

## **Chapter 1**

### **Behavioural interventions for HIV prevention**

#### **1.0 Introduction**

Acquired immune deficiency syndrome (AIDS) was first described in homosexual men, hereafter referred to as gay men, in the United States in 1981 (Gottlieb *et al.* 1981). The first case report of immuno-suppression in a gay man in the United Kingdom appeared in *The Lancet* later the same year (DuBois *et al.* 1981). The causative agent was first identified in 1983 and was subsequently named human immunodeficiency virus (HIV) (Gallo *et al.* 1983). Since then, HIV/AIDS has spread globally; however, in the UK, gay men have been, and continue to be, disproportionately affected (Health Protection Agency *et al.* 2003). By the end of the 1990s homosexually acquired HIV no longer accounted for the majority of new HIV diagnoses each year, but gay men continued to be the group with the greatest risk of acquiring the infection in the UK (Miller *et al.* 1999).

## **1.1 Behavioural interventions and the challenge of preventing HIV/AIDS**

Putting in place effective HIV prevention continues to pose daunting challenges. These challenges cut across public health, medical, social, economic and political decision making (Mann 1994; Weiss *et al.* 2001). In addition to awareness raising, health education, condom distribution and other community-based programmes, targeted behavioural interventions have become a popular way of supporting individuals trying to initiate and maintain behaviour change to reduce their HIV risk (Coates *et al.* 1996a).

Individually targeted behavioural interventions aim to reduce specific behaviours that place a person at greater risk of acquiring HIV or, if already infected, of passing it on (Bonell & Imrie 2001). But as much as research has identified those behaviours that increase individual risk of becoming HIV infected, it has also demonstrated that initiating and sustaining sexual behaviour change over time is an ongoing personal challenge. The level of individual behaviour change required to stop the spread of HIV is a challenge on a scale medicine, public health and legislative policy makers have not previously encountered (Garfield 1994; Kelly 1995; Shilts 1987). The complexities involved in initiating and maintaining sexual behaviour change are still only partially understood. Although new interventions are continually being developed and implemented, their specific and relative contributions to overall HIV prevention remains under evaluated (O'Leary *et al.* 1997; Oakley *et al.* 1995; Stephenson 2003). Twenty years into the HIV pandemic, epidemiological evidence has shown that behaviour change to reduce risk of HIV infection is not simple, certain or permanent, and bringing about sustained individual level behaviour change remains the most enduring of HIV's prevention challenges (Gomez 2001).

## **1.2 Genitourinary medicine clinics and HIV prevention**

Genitourinary medicine (GUM) clinics have been the locus of most clinical and behavioural HIV research in the UK. More recently they have become one of the focal points of research

involving HIV prevention and sexual health promotion. This has been partly driven by a recognition that specific groups of GUM clinic users are at greater risk of poor sexual health, sexually transmitted infections (STI) and HIV infection than others in the general population (Dodds *et al.* 2000; Imrie & Johnson 2001; Johnson *et al.* 1994).

Until the 1980s, the sexual health promotion activities in most GUM clinics were restricted to primary prevention through contact tracing based on legislative requirements, and secondary prevention in the form of disease screening and treatment of infected individuals (Adler 1980; Adler 1999). The advent of HIV changed this almost beyond recognition (Adler 1999). GUM clinics have taken on more proactive roles in primary HIV prevention and most provide a range of clinical and social care to those living with HIV (Adler 1999; Department of Health [DoH], 2001).

Most community-based primary HIV prevention with gay men has been undertaken by voluntary sector agencies, but GUM as a medical specialty and GUM clinics in particular, have taken on increasingly important roles by providing more intensive face-to-face interventions, disease testing and treatment and care services (DoH, 2001). AIDS historians note that this is partially an historic legacy. Laws dating back to the 1920s protected the identities of people attending GUM clinics and the speciality has a long tradition of client protection and confidentiality (Adler 1980; Berridge 1996). In the years prior to HIV, GUM clinics were for many gay men their main point of formal contact with the National Health Service (NHS) (King 1993). During the very early days of HIV, GUM clinicians, gay and lesbian activists, community organisations and the influential gay press worked together to meet the gay community's information needs (Berridge 1996; Garfield 1994). It was, therefore, a logical progression that treatment and prevention activities relating to this socially stigmatised infection would be cared for in the GUM setting. This also meant that GUM clinics became the centre of much individually focused HIV prevention activity,



particularly following the widespread introduction of HIV testing (Dawson *et al.* 1994; Berridge 1996; Flowers *et al.* 2000). As the UK's HIV epidemic has evolved, the need for more intensive and client-centred prevention interventions has increased. Until the mid to late 1990s these were almost exclusively provided in the context of GUM settings.

### **1.3 Setting for the randomised controlled trial – the Mortimer Market Centre**

The main part of this thesis describes a randomised controlled trial (RCT) evaluation of a behavioural intervention targeting 'high-risk' gay men attending GUM clinic services. The trial was undertaken at the Mortimer Market Centre, then the Department of Genitourinary Medicine of the University College London Hospitals NHS Trust. The Mortimer Market Centre is one of the largest sexual health facilities in Europe and among the busiest GUM clinics in the UK. There is something of an affectionate historic link between the Mortimer Market Centre and London's gay community. This is partly due to its physical location in close proximity to London's so-called 'gay village' in Soho, but also through its provision of sympathetic, quality sexual health and HIV care. In addition to the routine sexual health and HIV outpatient services, there is a weekly clinic targeting young gay men known as the Axis Clinic (Bean *et al.* 1999), as well as outreach satellite services for commercial sex workers and the homeless (Whittaker *et al.* 1996).

All clinical staff at the Mortimer Market Centre are trained to provide sexual health and HIV prevention interventions and health education in line with their clinical roles. This includes providing generic health promotion and HIV prevention information, and demonstration and distribution of condoms (Weatherburn *et al.* 1997). As in most GUM clinics, the Mortimer Market Centre's Health Advisors are central in assisting with partner notification, pre- and post-HIV test counselling and other brief counselling interventions (Mortimer Market Centre 1998). Treatment for psychological problems and more intensive prevention work is undertaken by senior Health Advisors and the clinical psychology team, mainly in ongoing

one-to-one sessions (Mortimer Market Centre 1998). A multi-session cognitive behavioural groupwork-based intervention for gay men was also available on a self-referral basis at the time of the study (Mortimer Market Centre, 1998; Billington & Wanigaratne 2000).

#### **1.4 Overview of the thesis**

The aim of this thesis is to describe the development, conduct and results of an RCT evaluation of a brief behavioural intervention targeting ‘high-risk’ gay men attending GUM clinics. However, in the context of a contentious and rapidly evolving field like HIV prevention, such a trial cannot be entirely separated from its wider social and research contexts. Therefore a secondary aim is to describe the background context within which the trial was undertaken and to examine the trial’s impact on local HIV prevention planning and provision, and on the wider prevention research agenda.

Chapter 2 describes the historic and research contexts that are part of the background to the study. The chapter starts from a global perspective, the focus then narrows to examine the rapidly changing prevention playing field, particularly in relation to evaluation of interventions and understandings of effectiveness. In Chapter 3 the spotlight is on HIV prevention for gay men in operation, and the evidence for its effectiveness, based on a critical review of the UK evaluation literature. This chapter highlights the value of the trial as a demonstration project – showing prevention commissioners and practitioners how rigorously obtained evaluation evidence can be used to identify those prevention interventions most likely to be effective and to offer ‘best value for money’ in the context of limited financial resources.

The next five chapters describe the actual RCT in detail. Chapter 4 summarises the development of the BIG Project Workshop intervention. The methodology of the trial and accompanying process and quality assurance evaluations are described in Chapter 5. Chapter

6 explains the conduct of the trial and Chapter 7 describes the trial's main results. In Chapter 8 the trial data are subject to further investigation and analysis to provide a more complete explanation of the results.

In Chapter 9, the concluding chapter, the focus returns to the wider context of HIV prevention and gay men and the wider research agenda in the UK. At the time of writing there are now a small number of completed evaluations of specific HIV prevention and sexual health interventions targeting gay men in the UK based on controlled or quasi-experimental evaluations (Elford, Bolding & Sherr 2001; Flowers *et al.* 2002; Williamson *et al.* 2001). This final chapter returns to the earlier theme of how extending our knowledge of HIV prevention effectiveness through rigorous evaluations should influence prevention planning and provision, and considers areas for further research.

## **1.5 Candidate's contribution**

I was originally employed as the trial coordinator and was not therefore directly involved in the overall study design, development of the original intervention, obtaining ethical approval or securing the initial funding. However, this does not mean that I did not make a significant intellectual contribution to the study and to the specific field of research more generally. This section outlines my personal contribution and intellectual input to the RCT described in the thesis.

### *Set-up of the study*

As trial coordinator I took overall responsibility for clinic liaison, development of study protocols including referral, inclusion and exclusion criteria, training in recruitment, follow up and retention procedures. With other investigators, I designed, developed and delivered the intervention facilitators' training and first authored the BIG Project Participant's

Workbook. I designed, wrote and coded all the participant questionnaires used in the study and performed one half of the data entry.

### *Implementation and data collection*

My main responsibility during the actual trial was to organise delivery of the intervention. I was also responsible for key aspects of recruitment, all aspects of follow up and overseeing the participant retention. With assistance from the Principal Investigator (Dr J M Stephenson), I wrote a successful funding application to allow us to undertake a cross-sectional postal urine survey and additional clinical follow up. I assumed overall responsibility for this work during Dr Stephenson's maternity leave. To confirm the accuracy of our incident STI endpoints, I worked with Dr Stephenson to negotiate use of a regional STI database, writing the original proposal to the regional GUM directorate and eventually preparing the data for the matching exercise.

### *Analysis of results*

The sample size calculation, randomisation scheme and analysis of the main results were all undertaken by the study statisticians. However, I did perform my own analysis of the main results (Chapter 7) and additional exploratory analysis to try to explain the study findings (Chapter 8). I was also wholly responsible for the design, conduct and analysis of the process and quality assurance evaluations described in Chapter 6.

### *Dissemination*

I have led on dissemination of the findings from the trial. I have presented the results in numerous local, national and international forums as both oral and poster presentations (see Appendix 1). I wrote the first draft of the main paper from the study, contributed substantively to two methodological papers, three review articles and have co-edited a

collection on the issues raised in experimental evaluations of sexual health interventions recently published by Oxford University Press (Appendix 1).

## **1.6 Conclusions**

HIV continues to present many challenges. As a discipline and area of scientific enquiry, HIV prevention is a field that is rapidly evolving and responding to these challenges. The descriptions contained in this thesis are intended to help increase our understanding of the interface between rigorous science and the social imperatives for effective prevention created by the HIV epidemic.

## **Chapter 2**

### **Historical background and research context**

#### **2.0 Introduction**

This chapter describes the background context to the RCT. The aim is to demonstrate that based on historic, epidemiological, social and research developments in the early years of the HIV epidemic, there was a strong case for undertaking an RCT of a suitable behavioural intervention that specifically targeted gay men attending GUM clinics. The chapter begins by briefly summarising early prevention responses and then examines the parallel developments in epidemiological and social scientific understanding of gay men's sexual behaviour. The final sections consider changing attitudes among researchers, prevention providers, community groups and funding organisations to HIV prevention research and intervention evaluation in the 1990s.

#### **2.1 Containment – The first prevention response**

Public health opinion has always emphasised the importance of preventing HIV infection rather than hoping for a cure. From the earliest days of the epidemic it was widely believed the responsible agent was sexually transmitted (Shilts 1987). But until such time as there was

a clear understanding of AIDS' aetiology, the only feasible prevention response was containment. This response often looked and felt socially draconian because there was no clear evidence that containment policies could effectively stem the epidemic (Garfield 1994; Shilts 1987). Containment measures varied from country to country, largely shaped by prevailing attitudes towards the groups most affected by HIV/AIDS. For example, internationally, the United States, Australia and some European countries refused entry to foreign nationals known to have HIV. While locally, legislators and public health departments closed down commercial gay venues like saunas and sex clubs and prohibited the sale of nitrate inhalants ('poppers') (Garrett 1994; Shilts 1987). Medicine, public health and government officials alike found themselves literally and figuratively, 'groping in the dark' with a new disease for which they had little to offer in the way of prevention advice – save abstaining from sex (Berridge 1996; Shilts 1987). It was months, in some cases years, before prevention moved on from containment approaches to health education approaches that sought to engender population level behaviour change.

In 1983, two years after the first UK case report, the only prevention information available to gay men was imprecise and little more than common sense. Leaflets circulated in London gay clubs that were simply poor photocopies of what was available on New York's gay scene. They hinted at the potential benefits of behaviour change, but in language that was veiled, vague and hardly likely to prompt sexual behaviour change – 'Have as much sex as you want, ... but with fewer people and with *healthy people*' (emphasis in the original) (Garfield 1994).

It is not surprising that the tone of these leaflets was less than persuasive. Firstly, in epidemiological terms, there was still uncertainty about the cause of AIDS. Secondly admonishments from authority figures to abstain from sex would have been received by most gay men with hostility or, at best, scepticism. The 1970s Gay Liberation Movement was still fresh in many gay men's minds. The achievements of the 1970s meant gay men were able to



be out and many were still 'intoxicated with their hard-won civil liberties' (Garrett 1994). Suggestions from public authority figures of the need for gay men to alter their sexual lifestyles were likely to be interpreted as 'excessively moralising' and an infringement of their sexual freedom (Garrett 1994; Shilts 1987).

## **2.2 First-generation HIV/AIDS prevention – Health education for gay men**

The first formal health education interventions for gay men were undertaken by gay community, voluntary sector and non-government organisations (King 1993; Shilts 1987). But in their respective histories of HIV/AIDS in the UK, Berridge and Garfield describe how it was GUM clinicians, gay and lesbian activists, community organisations and the gay press working together that produced the first accurate information about HIV/AIDS for gay men (Berridge 1996; Garfield 1994). This eclectic collaboration succeeded in raising awareness, allaying fears and suspicions about the medical and public health establishments, and promoting 'safer sex' strategies – primarily using condoms for anal sex – in a viable and acceptable way, long before there was any action on the part of UK statutory authorities (Berridge 1996).

The UK government's first general-population AIDS awareness campaign was in 1986 (Berridge 1996). The government provided some financial support to voluntary sector groups working with gay men, mainly the Terrence Higgins Trust, but at this stage would not allow its own agencies to develop or deliver HIV education specifically targeting gay men. It was not until 1989 that UK statutory health education providers produced and distributed their first HIV prevention directed at gay men (Berridge 1996; Garfield 1994; King 1993; Wellings & Field 1996).

### **2.3 Epidemiological understanding and observed sexual behaviour change**

As messages about AIDS' aetiology, transmission routes and ways of reducing risk trickled down, social scientists and epidemiologists began to see the first evidence of population level sexual behaviour change among gay men. In the United States, large repeat cross-sectional and cohort studies observed dramatic declines in self-reported unsafe sexual practice, increased condom-use for anal intercourse (AI) and overall reduced numbers of sexual partners (Beltran *et al.* 1993; Kaslow *et al.* 1987; McKusick *et al.* 1990; Stall *et al.* 1989). Similar observations were reported from the UK and other developed countries (Johnson & Gill 1989; Kinghorn 1994; Kippax *et al.* 1993; van de Laar *et al.* 1990). These reports appeared to confirm what was already apparent on the ground, that is, that gay men 'on the scene' had become generally well informed about HIV and safer sex, had responded to AIDS' devastating impact on their friends and communities and, most importantly, were amenable to behavioural change (Garfield 1994). Uniquely in the UK, there was also wide acknowledgement that the generally negative press coverage of AIDS and gay men contributed to successful dissemination and adoption of safer sex behaviours (Berridge 1996; Garfield 1994; Weller *et al.* 1984).

Although cumulative numbers of diagnosed HIV cases continued to rise steeply when antibody testing became widely available, the public health dividends of gay men's changed sexual behaviour were confirmed by significant declines in the diagnosis rates of some homosexually acquired STI (Evans *et al.* 1993; Miller *et al.* 1995). There is now evidence to suggest that there was also a slowing in the HIV incidence rate as well (Gupta *et al.* 2000; MacDonald 2000; PHLS AIDS and STD Centre 2000).

### **2.4 The 'relapse' debate**

However, the decline in STI incidence was relatively short-lived. As early as 1989, small but significant increases in some high-risk sexual behaviours and in some STI, including HIV,

were observed in several important sentinel studies from the United States, the Netherlands, Australia and the UK (de Wit *et al.* 1993a; Evans *et al.* 1993; Forsyth *et al.* 1990; Gupta *et al.* 2000; Handsfield *et al.* 1989; van den Hoek *et al.* 1990). Reports from several cohort studies, set-up in the mid 1980s, confirmed what disease surveillance was already suggesting, that is that some gay men who had initially adopted safer sex were reverting back to their old practices (Adib *et al.* 1991; de Wit *et al.* 1993b; Stall *et al.* 1990). 'Relapse' and 'relapsing to unsafe sex' were unfortunate terms used to describe this apparent backsliding from scrupulous adherence to safer sex (Adib *et al.* 1991). Relapse in particular was condemned for its pejorative tone and inference that there was some loss of control or psychological short circuiting involved when gay men engaged in unprotected sex rather than an informed choice, desire or trust (Davies 1993; Davies 1992; Ekstrand 1992; Ekstrand *et al.* 1993; Hart 1992).

The relapse question engendered controversy and debate between academics and among community and activist groups about the ultimate goals of HIV prevention. But the phenomenon it described highlighted three critical facts about scientific approaches to HIV prevention. Firstly, that sustaining sexual behaviour change was difficult and there was no guarantee that behaviour change once adopted was permanent. Secondly, there was significant variation in how different fields of scientific and social scientific enquiry viewed and understood HIV, sexual behaviour, safer sex and risk reduction. And thirdly, that no discipline held a monopoly on understanding sexual behaviour, safer sex or risk reduction. In short, what the relapse debate highlighted most starkly was that, to be effective, HIV prevention needed input from different disciplines, working together on an equal footing (Donovan & Ross 2000; Ekstrand *et al.* 1993).

There were other beneficial spin-offs of the relapse debate. Among them was encouragement for researchers to expand the scope of their enquiries beyond mechanistic sexual behaviour surveys to include exploration of other issues around HIV prevention for gay men, such as

barriers to adoption and maintenance of safer sex and condom-use (Fitzpatrick *et al.* 1989a; Fitzpatrick *et al.* 1990). The new research spawned by the relapse debate involved delving into new areas of social epidemiology including the nature of gay men's relationships, social norms within gay communities and the physical and social context of where sex occurs (Fitzpatrick *et al.* 1989a; Fitzpatrick *et al.* 1989b; Hart *et al.* 1990; Hart *et al.* 1993). Researchers believed the additional information generated from this research could help devise prevention strategies that incorporated both behaviour change and risk reduction, rather than simply education and awareness raising (Ekstrand *et al.* 1993; Ekstrand 1992; Hart 1995; Hart & Boulton 1995; Hart 1996; Kippax *et al.* 1993).

## **2.5 Second-generation HIV prevention – behavioural interventions and risk reduction**

While the relapse debate helped to broaden HIV prevention's epistemological base, on the ground it was increasingly clear that not all gay men were capable of constantly adhering to prescriptive safer sex doctrines – '100% condom-use, 100% of the time' – with every partner, and for ever. Maintaining condom-use for an apparently indefinite period was not popular and, for some, not possible. One American cohort study reported that approximately half its participants failed to maintain safer sex at least once in a two-year follow up period (Adib *et al.* 1991). A seminal Australian study highlighted the logic and 'safety' of unprotected anal sex within the context of monogamous relationships where both partners knew they were HIV negative based on repeated antibody tests, and where there was explicit agreement that any sex outside the relationship was restricted to 'safe sex' (Kippax *et al.* 1993). 'Negotiated safety', as this practice became known, offered individual and public health benefits and an alternative to indefinite condom-use for men in relationships (Billington *et al.* 1995; Kippax *et al.* 1993).

Other risk reduction strategies of this type had much to offer gay men frustrated by condom-use and the apparent lack of advance towards a vaccine or cure (King 1993; Kippax *et al.* 1993; Garfield 1994; Berridge 1996). But among UK public health and HIV prevention practitioners there was some reservation about adopting or promoting them too quickly. About the same time as Kippax *et al.*'s work was being heralded as an important prevention advance, UK studies showed the first significant year-on-year increases in homosexually acquired rectal gonorrhoea, which was considered by many to be the best proxy marker for recent unsafe sexual practice (Singaratnam *et al.* 1991; Young *et al.* 1991). There were also increases in HIV prevalence among younger gay men (< 25 years) attending GUM clinics, based on unlinked anonymous seroprevalence surveillance data (DoH 1994; Evans *et al.* 1993). These data appeared to confirm that maintaining condom-use was not only a problem among older gay men, but also for younger homosexually active men, many of whom had become sexually active in the era of AIDS (Adib *et al.* 1991; Boulton *et al.* 1992; Evans *et al.* 1993; Imrie *et al.* 1999a; MacKellar *et al.* 1996). Dealing with such changes in the context of gay men's HIV risk practices would require additional prevention work and new approaches.

One possibility, promoted in Australia, would be to implement strategies based on overall risk reduction rather than exclusively condom-use (Kippax *et al.* 1993; Kippax *et al.* 1997).

Strategies being promoted, such as negotiated safety, originated in observations of how gay men adapted their sexual behaviour to the threat of HIV/AIDS. Other possibilities included more carefully targeted behavioural interventions, such as those based on the growing body of social scientific and psychological research on the barriers to, initiation and maintenance of sexual behaviour change (Bonell & Imrie 2001; Coates *et al.* 1989; Coates *et al.* 1996b; Fitzpatrick *et al.* 1989a; Fitzpatrick *et al.* 1990; Fitzpatrick *et al.* 1991 Gold & Skinner 1991; Hart *et al.* 1993).

In the wake of the relapse debate more research was directed towards identifying predictors of safe and unsafe sexual behaviours, as well as the contributing situational and cognitive factors (de Wit *et al.* 1993b; Fitzpatrick *et al.* 1989a; Fitzpatrick *et al.* 1990; Fitzpatrick *et al.* 1991; Gold & Skinner 1993; Gold & Skinner 1992; Kelly *et al.* 1989; Kelly *et al.* 1991). The body of work suggested that, at a population level, safer sex was widely and fairly consistently practised, but lapses and relapse were common and sometimes premeditated, particularly among men in primary relationships (Fitzpatrick, *et al.* 1991; Gold & Skinner 1993; Kelly *et al.* 1991; Kippax *et al.* 1993; Weatherburn *et al.* 1992).

Some behavioural scientists were eager to develop HIV prevention interventions that were based on models and theories from clinical and social psychology, and that worked effectively to produce behaviour change in relation to other health conditions (Catania *et al.* 1990; Kelly *et al.* 1993; Valdiserri *et al.* 1992). These researchers argued that carefully conceived, closely targeted behavioural interventions could overcome the shortcomings of HIV education by directly addressing behaviour change without stigmatising or pathologising those who experienced difficulties adopting or maintaining safer sex (Catania *et al.* 1990; Coates *et al.* 1996b; Kelly *et al.* 1993; Kelly *et al.* 1991).

## **2.6 More effective prevention interventions needed**

The first-generation health education campaigns demonstrated that in a time of crisis, education, when provided by credible sources, was on its own enough to engender remarkable levels of sexual behaviour change (Fitzpatrick *et al.* 1990; Stall *et al.* 1989). But as the disease surveillance data from the early 1990s indicated, in the future gay men's HIV prevention would be considerably more complicated (Coates *et al.* 1996b; DiClemente & Peterson 1994). In hindsight it was probably naive to have believed that repeating the same message over and over in different guises would have been enough to sustain population-level behaviour change indefinitely (Becker & Joseph 1988; Hart 1996a; Hart 1996b; Hart 1989).

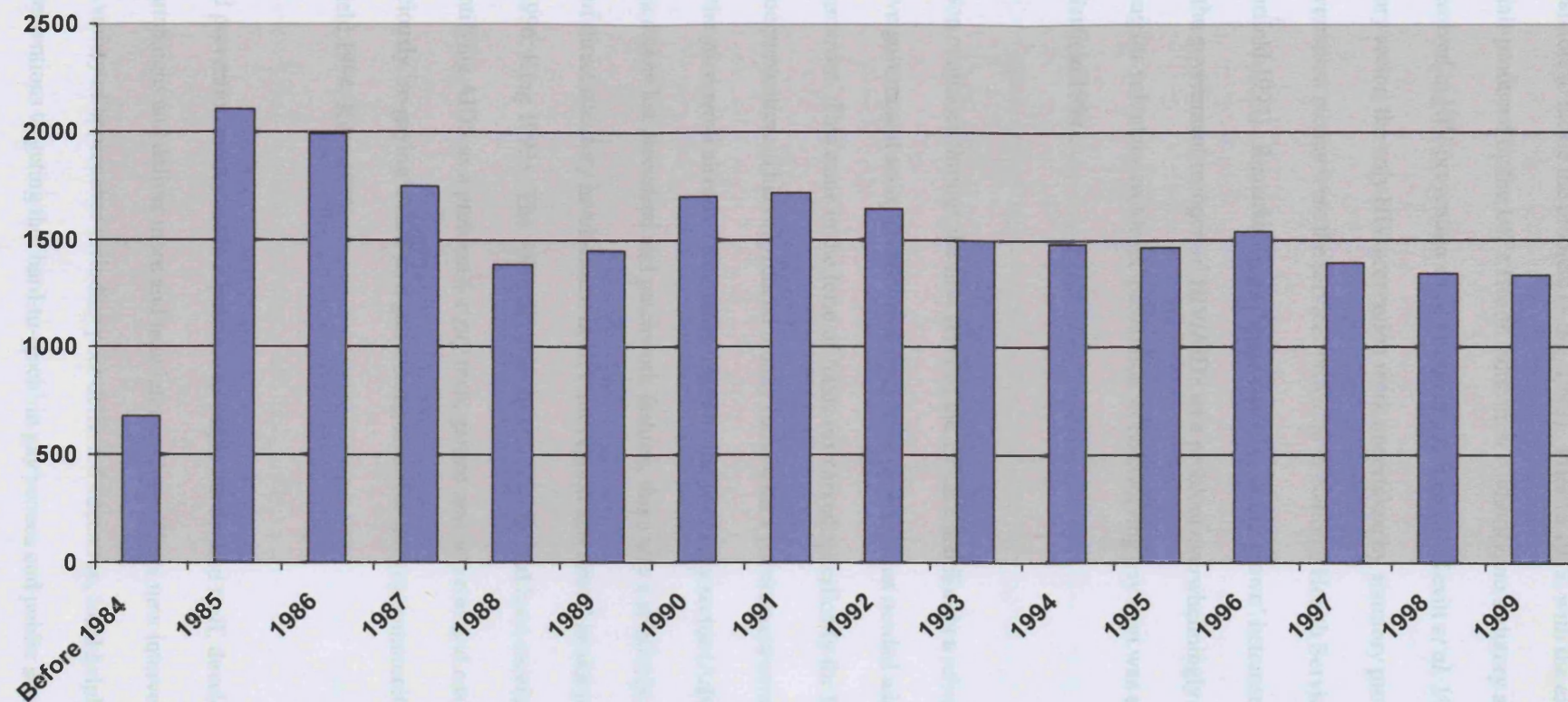
As safer sex became the perceived social norm among gay men, those who encountered difficulty either adopting or sustaining condom-use began to feel stigmatised within their own communities (King, 1993).

UK surveillance data showed (see Figure 1) that early prevention campaigns appeared to achieve their maximum impact in the early 1990s when the number of newly diagnosed HIV infections began to show signs of stabilising. Figure 1 shows the total number of new HIV diagnoses presumed to be homosexually acquired in England and Wales from 1984 to 1999 (PHLS AIDS and STD Centre 2000). The initial steep incline corresponds to the introduction of widespread HIV testing (Dawson *et al.* 1994). Following a brief decline, annual new diagnoses appear to rise again and then stabilise at around 1500 each year for the remainder of the decade. The initial suggestion that this might reflect the effect of an ageing cohort of HIV infection coming forward to test has since been dismissed by research which showed that, at least until 1997, the overall size of the prevalent pool of HIV infection and the number of incident infections annually remained fairly constant (Gupta *et al.* 2000; MacDonald 2000; Miller *et al.* 1999). Combined behavioural and HIV surveillance data showed that the need for effective HIV prevention interventions was still acute (Hart *et al.* 1990; Hart *et al.* 1993). The evolving approach being adopted in the UK was to have behavioural interventions operating alongside risk reduction interventions and continued health education to provide an overarching and comprehensive HIV prevention strategy that could support all those at increased risk (Berridge 1996; DoH 1994; DoH 1995; Garfield 1994; Hart 1995; Hart 1996b).

## **2.7 The UK's evolving prevention debate**

Like other countries, the UK's first gay men's HIV prevention work was largely undertaken by community and voluntary sector agencies (Berridge 1996; Rotello 1998; Shilts 1987; Wellings & Field 1996). However, two factors distinguish the gay men's HIV prevention in the UK from other countries: firstly, the time taken by central government to accept that gay

**Figure 1:** Number of new HIV diagnoses presumed to be homosexually acquired, by year of report



Source: PHLS AIDS and STD Centre, Communicable disease Surveillance Centre and Scottish centre for Infection and Environmental Health. (2000) Unpublished Quarterly Surveillance Tables No. 45, 99/4 Table 9a.



men were the population most seriously affected by HIV, and secondly, the limited resources it made available to tackle the problem (King, 1993). Prior to 1989, with the exception of a few materials produced by the UK's Health Education Authority, no statutory agencies were directly involved in HIV prevention work targeting gay men (McKevitt *et al.* 1993). Outside the voluntary sector, the only HIV prevention work undertaken by statutory providers using central government money were the services provided in National Health Service GUM clinics (Garfield 1994). Remarkably, as the spectre of a 'home-grown' heterosexual epidemic faded and the government recognised HIV/AIDS as a problem overwhelmingly affecting gay men, funding for voluntary-sector-led prevention work involving gay men was actually reduced (Garfield 1994).

This situation continued through the first years of the 1990s when finally a reluctant Conservative government accepted HIV as a significant problem that needed additional financial resources. This came in the form of funds earmarked specifically for HIV treatment and care, and prevention. This ring-fenced money came with a government commitment to encourage the good work already being undertaken by the voluntary sector (Adler 1999). As a result, in a somewhat piecemeal and patchwork fashion, there was a relatively rapid expansion of direct statutory involvement in HIV prevention and sexual health promotion (Berridge 1996; King 1993). The voluntary sector, which so far had been careful to avoid too closely identifying AIDS as a problem for gay men, gained new impetus and cash, and set about consciously 're-gaying' AIDS as a galvanising issue for the gay community (Crosier 1996; Garfield 1994; King 1993).

Ring-fenced prevention money made it possible to employ dedicated staff, develop innovative education campaigns and deliver more and new interventions. These new interventions employed a variety of approaches including peer-delivered education, local helplines, outreach interventions targeting the 'hard-to-reach' in gay venues and public sex

environments (PSE) and dedicated GUM clinical services (see, for example, Bean *et al.* 1999; Deverell & Rooney 1994; French *et al.* 1997; Hartley *et al.* 1999; Weatherburn 1997a).

However, there was a catch attached to the new central government resources. It came in the form of annually renewable contracts and performance measurement based on outcomes (Bonell 1995).

Evaluations to show how government money was being used and how new interventions were working was a legislative requirement imposed on almost all statutory purchasers of prevention services for example the Department of Health, Health Education Authority and Regional Health Authorities – that in turn affected prevention providers. Up to this point most HIV prevention evaluations were essentially monitoring and activity reports that specified the numbers of condoms distributed or the number of outreach contacts made rather than giving any estimate of an intervention's actual impact on risk behaviours or HIV transmission, which was what statutory funders now required (Deverell 1995; McKevitt *et al.* 1993). As McKevitt *et al.* concluded in their 1993 review of HIV prevention evaluations, and others would argue stridently later, virtually all evaluations claimed the intervention *worked* in some sense, but defined measures of how much risk reduction could be attributed to any single intervention were almost always missing (Hart 1995; Hart 1996b; Hart 1997; McKevitt *et al.* 1993). Most prevention practitioners had limited experience of rigorous evaluations and felt it would not be possible to demonstrate their interventions had a measurable impact on either sexual behaviour or HIV transmission, particularly given the short contract periods and the time needed to undertake full-scale outcome evaluations (Bonell & Devlin 1996; Deverell & Rooney 1994; McKevitt *et al.* 1993).

Prevention providers' objections to the new evaluation requirements were understandable. The one-year contract period was short and possibly not long enough to produce measurable prevention outcomes. What constituted appropriate outcomes was generally poorly

understood by purchasers and providers alike (Bonell 1995; Bonell & Devlin 1996; Hart 1996b; Hart 1996c) and most community-based organisations had neither the research skills nor the financial resources to undertake large-scale outcome evaluations. Important questions about whether single interventions could produce the kind of effectiveness evidence funders wanted remained largely unanswered (Hart 1995). And given the government's longstanding neglect of the problem of HIV and gay men, they questioned whether it was not more important to be seen to be doing something rather than using limited resources to produce what would at best be weak indicators of an intervention's long-term effectiveness? (Aggleton 1994)

Similar questions were raised by national and local funders, as well as policy makers and academics (Hart 1995; Hart 1997). The research response was an initiative launched by a group of academics commissioned by the Medical Research Council, the Health Education Authority and the North Thames Regional Health Authority to conduct a series of critical systematic reviews of the evidence for the effectiveness of HIV prevention and sexual health education interventions more generally (Oakley *et al.* 1995a; Oakley *et al.* 1995b; Oakley *et al.* 1996; Oakley & Fullerton 1994; Peersman *et al.* 1996; Peersman *et al.* 1999). Over the course of several reviews, the group consistently concluded that the majority of evaluation research in health promotion was poorly conducted; that it could not demonstrate effectiveness; that it did not make sufficient use of behavioural science theory, and that it rarely tested interventions in carefully designed studies, specifically RCTs (Oakley & Fullerton 1994; Oakley *et al.* 1995a; Oakley *et al.* 1995b; Oakley *et al.* 1996; Peersman *et al.* 1996; Peersman *et al.* 1999). The recommendations and conclusions reached by Oakley *et al.* were perhaps more prescriptive than those of their American counterparts involved in a similar exercise, who simply appealed for innovative behavioural interventions to be subjected to more rigorous evaluation (Coates *et al.* 1996b).

## 2.8 Evidence-based HIV prevention

Underpinning Oakley's reviews was a broader movement in medicine and public health to make medical practice and health care provision more evidence-based (Hart 1995; Hart 1996a; Hart 1997). As with medical and pharmaceutical interventions, rigorous evaluations that employed RCT methodologies were considered the 'gold standard' for obtaining evidence for healthcare decision-making. Oakley's reviews argued the same principle should be applied to health promotion and, particularly, HIV prevention interventions (Oakley *et al.* 1990; Oakley *et al.* 1995a; Oakley *et al.* 1995b; Oakley *et al.* 1996). As a result of these parallel developments, key funding bodies in the UK and the United States agreed that rigorous evaluations of behavioural interventions and, specifically, sexual health and HIV prevention interventions, should become priorities (National Institutes of Health 1997).

At the same time as Oakley *et al.* were arguing for evidenced-based interventions and more randomised trials, other groups of academics argued that health promotion interventions, and sexual health promotion interventions in particular, were inherently unsuitable for RCTs (Aggleton 1994; Aggleton 1999; Kippax & van de Ven 1998; Tones 1997). At the core of their argument was the view that in the health promotion context such methodologies were unethical, costly, time consuming and not really worthwhile given the presumed complementary effect of different interventions within entire prevention programmes (Aggleton 1994; Aggleton 1999; Kippax & van de Ven 1998; Tones 1997). Polarisation began to appear within the prevention community, with public health scientists and funders frequently squaring off against more traditional health promotion researchers, prevention providers and community groups (Kippax & van de Ven 1998; Tones 1997). The debate continues today (Bonell *et al.* 2003; Kippax 2003; Ross & Wight 2003).

## **2.9 Conclusions**

This chapter has attempted to situate the RCT, which is the subject of this dissertation, in its appropriate historical and research context, and to delineate its public health perspective.

From a public health perspective, three features of the evolving HIV epidemic provide the main impetus for undertaking the study. Firstly, despite significant expenditure of resources and energy, evidence that HIV prevention interventions targeting gay men were effective was weak. Gay men continued to be disproportionately affected by AIDS and HIV and there was no evidence of a reduction in HIV incidence. Secondly, without the benefit of a vaccine or cure, sustained behavioural change would remain the cornerstone of effective prevention, and targeted theory-based behavioural interventions offered a potentially important means to achieve this. Thirdly, in order to ensure best use of resources, HIV prevention interventions needed to be evaluated for their effectiveness, ideally under rigorous conditions, so that when implemented in communities, funders and providers could be confident about the value and effectiveness of their work.

## **Chapter 3**

### **Descriptive review of UK gay men's HIV prevention and evaluation**

#### **3.0 Introduction**

In the 1990s there was growing interest in the actual functioning and effectiveness of HIV prevention (Hart 1997). This chapter looks at how HIV prevention for gay men was being operationalised on the ground in the UK and what evidence there is that it was contributing to reduced HIV transmission and reduced sexual risk behaviour. The chapter is based on a descriptive review of the UK literature on HIV prevention practice and evaluation. The purpose is to illustrate where targeted behavioural interventions fit in HIV prevention's rapidly expanding repertoire of activities, and how an RCT would contribute to the evidence base and the increasing support for rigorous evaluation.

#### **3.1 Aim of the review**

The aim of the review is to describe the evolution of gay men's HIV prevention and evaluation in the UK prior to and during the conduct of the RCT. It focuses exclusively on HIV prevention in the UK and is limited to evaluation reports from the published and 'grey'

literature. Unpublished reports, such as those prepared for funders or local Health Authorities, rarely give adequate detail to assess an intervention's impact on either transmission or behaviour, and are therefore excluded. Selected example interventions have been chosen for more complete description and examination to illustrate key points in relation to intervention development and evaluation. Unlike published systematic reviews of HIV health promotion interventions for gay men or reviews of 'good practice', discussion here is restricted to description and critical appraisal of the interventions themselves and the evaluation designs (Holland *et al.* 1994; Johnson *et al.* 2003; McKevitt *et al.* 1993; Oakley *et al.* 1996).

### **3.2 Methodology**

Evaluation reports in the scientific literature generally provide the most comprehensive descriptions of interventions, evaluation methods and results. Where additional information was available, for example from descriptive papers or process evaluations, this was also examined, particularly in the case of the selected examples reported in Tables 1 and 2.

Interventions were eligible for inclusion in the review based on where they took place (i.e. the UK) and the target population (i.e. gay, bisexual and other homosexually active men). Given the small number of interventions targeting gay men with published evaluations undertaken in the UK, it was not necessary to restrict inclusion further. Search strategies similar to those used by Oakley *et al.* and the Centers for Disease Control and Prevention (CDC) HIV/AIDS Prevention Research Synthesis Project were initially used (CDC 1999; Holland *et al.* 1994; Oakley *et al.* 1995b; Oakley *et al.* 1996). However, the majority of UK evaluation reports were in the 'grey' literature, and consequently identification of these studies relied heavily on hand-searching and communication with colleagues in the field.

Electronic and hand-searching results were collated and a set of illustrative examples was selected for more careful examination and description (see Tables 1 and 2). The selection of

examples was based entirely on their illustrative value. However, this did not mean worthy evaluation reports were ignored or overlooked because, on the whole, there was a serious lack of quality published evaluation reports ((Hart 1996a; Hart 1997; Oakley *et al.* 1996).

### 3.3 Search Strategies

Initial electronic search strategies were designed to identify the largest possible number of reports of HIV and other general health promotion interventions targeting gay men (see Appendix 2). The first objective of the search was to ensure all studies identified in earlier systematic reviews and review articles were captured and then to focus the search for publications relevant to the specified context (CDC 1999; Friedman & O'Reilly 1997; Kalichman & Carey 1996; Kegeles & Hart 1998; Oakley *et al.* 1996). Filters were added to limit the electronic searches to reports from the UK. Finally, the Cochrane Library search history was applied to the full list of reports to single out those considered RCTs according to these criteria (see Appendix 2). Computer and worldwide web searches included Silver Platter MEDLINE, EMBASE, PsychLIT and AIDSLINE for the period 1985 through to end of 2000. Evaluations with findings published prior to end of 2000, or where publication was pending (i.e. *in press*), were followed for additional reports through the end of July 2002. Requests were made to the National HIV Prevention Information Service (NHPIS, Health Development Agency for England) and the Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre) (Social Science Research Unit, Institute of Education, University of London) for evaluation reports added to their databases since 1994. Conference abstracts (International AIDS Conference, 1993–2000; US National HIV Prevention Conference, 1998–2000) were searched electronically using AIDSLINE and the Centers for Disease Control and Prevention electronic conference abstracts ([www.cdc.gov/hiv/conferen/html](http://www.cdc.gov/hiv/conferen/html) cited 21.03.01). Abstracts from other conferences were also hand-searched (International Society for Sexually Transmitted Diseases Research, 1995, 1997, 1999; International Conference on the Bio-Psychosocial Aspects of AIDS - AIDS



Impact, 1995, 1997, 1999; Annual Spring Meetings of the Medical Society for the Study of Venereal Diseases (MSSVD), 1996–2000; and the UK Community HIV/AIDS Prevention Strategy (CHAPS) Gay Men’s HIV Prevention Conferences, 1998–2000), and materials were sought from colleagues working in the field.

### **3.4 Search results**

Electronic searching identified 3048 publications that described education, clinical, technological, behaviour studies or intervention evaluation reports specifically involving gay men. Filters to identify UK studies reduced this to 110. Using the initial search results (N = 3048) and filtering with the Cochrane Library search history to identify the randomised controlled trials produced a total of 15 studies, none of which had been undertaken in the UK. Requests to the NHPIS and EPPI-Centre identified 6 studies (5 and 1 respectively). Two of these had not been identified by the electronic searches. Searching conference abstracts identified a further 89 prevention intervention reports, including numerous reports from the same study. Almost all these additional reports were from a number of recently initiated multi-site experimental studies in the United States. Consultation with colleagues produced reports from one further study from the United States and two UK studies with results *in press* at the time.

### **3.5 Selected examples**

From the full search results, twelve studies were selected because of their illustrative value for more thorough description and examination. Eight describe interventions that give a general sense of UK HIV prevention targeting gay men and the kinds of evaluations being undertaken in the early to mid 1990s (see Table 1). The four other studies selected all started after the instigation of this project (1995). They are presented separately in Table 2. These studies were subjected to closer examination because, according to the authors, they met Oakley *et al.*’s criteria of *methodologically sound* evaluations (see Figure 2), and because

they illustrate how prevention evaluation approaches and literature in the UK changed in the second last half of the 1990s (Hart 1995; Hart 1996a).

**Figure 2:** Criteria for ‘methodologically sound outcome evaluations’ and ‘rigorous evaluations’ – based on Oakley et al. (1996) and the CDC HIV/AIDS Prevention Research Synthesis Project (1999)

**Oakley et al.’s criteria for ‘methodologically sound’ studies**

1. Employ an equivalent control or comparison group
2. Provide pre-intervention data
3. Provide post-intervention data
4. Report on all pre-selected outcomes

**CDC Prevention Research Synthesis Project criteria for ‘rigorous evaluations’**

1. Random assignment to intervention and comparison groups with
  - Pre & post data *or*
  - Post-only data
2. Non-random assignment to intervention and comparison groups with
  - Pre & Post data *and*
  - No apparent assignment bias *or*
  - Adjustment for apparent assignment bias

### **3.6 Presentation of results**

The selected examples are presented in Tables 1 and 2 and discussed in the text in three sections. The first section uses the examples to illustrate the development of HIV prevention targeting gay men in the UK. The second describes the evolutionary development of HIV prevention evaluation as research area, and the third examines the studies deemed by the authors to be *methodologically sound* using Oakley et al.’s criteria (see Figure2) (Oakley et al.1996).

### **3.7 Development of UK HIV prevention targeting gay men**

By the mid to late 1990s gay men's HIV prevention in the UK was a multi-method, theoretically sophisticated undertaking that involved diverse providers and delivery of multiple interventions in a variety of settings.

#### *Expansion and diversification*

The significant expansion in gay men's HIV prevention largely appears to have coincided with the introduction of ring-fenced funding (Garfield 1994). In 1992, a national survey found that among 224 UK agencies involved in HIV prevention work, 70% (157/224) did no specific prevention work with gay men (King *et al.* 1992). But within five years every statutory health promotion service and most voluntary agencies had at least one nominated worker responsible for gay men's HIV prevention and some employed entire teams of gay men's HIV prevention specialists (e.g. Camden and Islington Health Promotion Service, City and East London Health Authority, East Sussex, Brighton and Hove Health Authority, Lothian Health Board (Scotland) and Terrence Higgins Trust).

Production of health education materials continued to be a cornerstone of prevention activity. However, in the 1990s it was extended and became more sophisticated (Deverell & Rooney 1994). Print media campaigns and press advertising became commonplace and multi-component media campaigns communicating more complex messages around risk reduction were employed (see, for example: Billington *et al.* 1995; Hickson *et al.* 1994; Kwok 1997; Kwok 1998; Sherr *et al.* 1999b).

Face-to-face interventions – professional and peer-delivered – became common as well. Some of these were adapted or 'hybridised' according to the local circumstances and need (King 1993). As Tables 1 and 2 illustrate, peer-led or peer-delivered interventions were particularly popular: in fact, nearly half of all the evaluation reports captured in the literature

**Table 1: Selected examples of published UK gay men's HIV prevention evaluation reports**

<b>PROJECT NAME</b>	<b>'KY Babies'</b>	<b>'Changing personal sexual practice'</b>	<b>'Men Only Clinic' (MOC)</b>	<b>'The HAPER Project'</b>
<b>Main intervention</b>	Training & supporting a team of safer sex peer educators (PEs)	Cognitive behavioural theory-based (CBT) groupwork based intervention	Designated GUM clinic sessions for men and staffed by men only	Peer-led sexual health promotion with young gay men
<b>Implementing &amp; evaluating agencies</b>	Camden & Islington Health Promotion Service & The HIV Project, London	Camden & Islington Community Health Services NHS Trust, London	Kensington, Chelsea & Westminster Health Authority, London	South & West Regional Health Authority, Southampton Gay Men's Health Project, University of Southampton
<b>Published references</b>	Deverell 1995	Billington <i>et al.</i> 1997a ; Billington & Wanigaratne 2000; Rodgers <i>et al.</i> 1997; Wanigaratne <i>et al.</i> 1997	Walsh <i>et al.</i> 1997	Shepherd <i>et al.</i> 1997
<b>Duration of project</b>	1993–1998	1992–2000	1993–1996	1995–1997
<b>Year of report</b>	1995	1997	1997	1997
<b>Evaluation design</b>	Exploratory qualitative process evaluation	Pre- & post-questionnaires (behaviour change & psychometric measures) & in-depth qualitative interviews	Retrospective case note review (2 yrs) MOC compared to routine service users	Process & quasi-experimental evaluation using knowledge, attitudes & sexual behaviour outcomes
<b>Intervention aims</b>	Improve sexual health & safer sex practices of young gay men (<25 years) by involving them in a peer-led safer sex education project	Change & enhanced probability of maintenance of personal safer sexual practices. Improve HIV & STI transmission knowledge	Bring more first-time attenders into the clinic	Train PEs to promote sexual health among men in community settings. Assess impact on knowledge, attitudes & safer sex practices
<b>Setting</b>	Community centres in north London	GUM clinic in central London	GUM clinic in central London	Gay venues & community settings in Southampton
<b>Intervention Population (N= )</b>	Mailing list = 58; 17 active members Mainly white, < 25 years old, living in central London	Evaluation sample was from one 6 month period in 1995 (N = 26). Mean age 35 years	209 attendances; 52% were homosexual men. Mean age 35 yrs	11 trained PEs; who recorded 43 contacts with mainly white < 25 years old who were active in local community

<b>PROJECT NAME</b>	<b>'KY Babies'</b>	<b>'Changing personal sexual practice'</b>	<b>'Men Only Clinic' (MOC)</b>	<b>'The HAPEER Project'</b>
<b>Comparison condition</b>	None	None	Sample of men attending routine service during the same period	Surveys of young gay men from a neighbouring community
<b>Description of the intervention:</b> (i.e. theory base, duration, facilitators, content & method of delivery)	Regular monthly meetings providing PEs with training in planning & practical skills. Based on models of peer-education, youth & community development & teambuilding. Facilitated by 4 trained youth workers	Small group workshop consisting of 6 sessions (20 hour). Based on Health Belief Model, group psychology, model of behaviour change & the relapse process model. Facilitated by trained counsellors. Individual sessions focused on: sexual risk-taking, safer sex & negotiation, body image, anxiety, coping styles & 'trigger' situations. Individual & group exercises, feedback & safe sex strategy development	Based in a 'mixed sex GUM clinic' (MSC). Intervention offered a dedicated clinical session for men and staffed by men only	Based on models of peer education & outreach. PEs trained in basic HIV and sexual health promotion over 3-month period. Intervention was developed using baseline data collected by PEs from sexual & social contacts & involved responding to contact's sexual health needs as per training. Average contact time 20 min. Process was repeated by PEs in future contact with same individuals
<b>Main findings</b>	Health promotion service was able to establish & maintain peer education group, to continually attract new members, provide formal training and support to the PEs. Project developed popular education resources for young (< 25 years old) gay men. Health Authority provided additional support for the project in the form of a designated staff member.	No significant changes in main behaviour outcomes (numbers of sex partners, time spent looking for sex, enjoyment of sex). Increased sense of control over sexual behaviour. Significant increase in self-efficacy/confidence immediately post-intervention; reduced at 3-month follow up. Non-significant positive trends in other psychological measures post-intervention. Qualitative interviews showed: group format was appropriate and that many men felt guilt around sexual risk-taking, which was a barrier to disclosure in the group setting.	Comparing between MOC and MSC attenders: non-significant difference in mean number of visits 1.9 vs. 1.6. 57% of MOC users vs. 24% of MSC users had not previously attended the clinic ( $p < 0.01$ ). MOC attenders significantly more likely to attend for asymptomatic STI screening, to be notified partners of index patients & to become psychosexual referrals than MSC homosexual male attenders.	Greatest population improvement was in knowledge & understanding of the behaviour risks for STI & HIV transmission of the PEs. Very little change in unsafe sexual behaviour – low at baseline, remained stable at follow up
<b>Conclusions</b>	Group met all of its aims well. Greatest benefits were for participants involved as PEs (no data available on community intervention recipients). Unclear what the level of diffusion/peer education was delivered in the community	Group-work format was appropriate for delivery of CBT-based intervention. Workshop produced positive changes in pre/post measures of 'Situational Self-confidence' which are good predictors of sustained behaviour change	MOC attracted new male patients. Increased the number of asymptomatic screens performed & number of psychosexual referrals. Provided useful first contact with GUM services for men who were otherwise unlikely to attend.	Peer-led sexual health promotion is flexible but intensive means by which to meet the varied needs of different local populations. PEs benefited through participation and communication skills acquired. Evaluation design was successful in determining impact of the intervention.

**Table 1: (cont'd) Selected examples of published UK gay men's HIV prevention evaluation reports**

<b>PROJECT NAME</b>	<b>'Hampstead Heath Project'</b>	<b>'Rubberstuffers'</b>	<b>'Try this HIV Test'</b>	<b>'Assert Yourself'</b>
<b>Main intervention</b>	Volunteer-led education outreach & condom provision in a public sex environment (PSE) in north London	Free condom distribution in London's gay commercial venues	Print media campaign	Small group assertiveness training delivered by trained facilitators
<b>Implementing &amp; evaluating agencies</b>	Gay Men Fighting AIDS (GMFA), UCL Medical School	RS Health & Sigma Research	Camden & Islington Health Promotion Service & Royal Free Medical School	Enfield and Haringey Health Authority & Sigma Research
<b>Published references</b>	Burnell <i>et al.</i> 1995; Dockrell, <i>et al.</i> 1996; French <i>et al.</i> 1998; French <i>et al.</i> 2000; Gay Men Fighting AIDS 1994; Mitchell 1996	Weatherburn 1997a; Weatherburn 1997b	Sherr <i>et al.</i> 1999a; Sherr <i>et al.</i> 1999b; Sherr <i>et al.</i> 1999c	Hickson & Boxford 1999; Hickson 2000
<b>Duration of project</b>	1993–2000	1993–1995 (subsidised sales) 1996–1999 (free distribution)	March–June 1998	1997–1999
<b>Year of report</b>	1994, 1995, 1996, 1997	1997	1999	1999
<b>Evaluation design</b>	1994–96 internal monitoring. 1997 external process evaluation involving questionnaire survey, depth interviews & participant observation	Pre & post cross-sectional surveys. In-depth interviews & focus groups	Surveys in GUM and HIV testing clinics measuring permeation, recall and impact of ad messages	Before & after outcome evaluation. Process data, pre/post questionnaires (including standardised assertiveness measure) & telephone depth interviews
<b>Intervention aims</b>	Provide regular, reliable source of condoms & trained volunteer outreach workers in a PSE setting	Reduce levels of unprotected anal intercourse (UAI) by increasing availability of free condoms in gay venues	Encourage consideration of HIV testing in light of treatment advances	Improve gay men's sexual choice & negotiation skills by teaching assertiveness training. Main outcomes related <i>assertiveness</i> of course attenders
<b>Setting</b>	Hampstead Heath - large PSE in north London	120 gay bars in central London (26 venues surveyed)	1 dedicated HIV testing centre & 1 GUM clinic, in central London	Various community venues including university facilities

<b>PROJECT NAME</b>	<b>'Hampstead Heath Project'</b>	<b>'Rubberstuffers'</b>	<b>'Try this HIV Test'</b>	<b>'Assert Yourself'</b>
<b>Intervention population (N= )</b>	From 1997 survey sample (N = 688) mainly white, London resident, mean age = 33; mainly 'gay' identified, >50% used Heath at least once a month	Based on survey sample (1996): Pre (N = 431) & Post (N = 624); >90% white; 84% London resident; >75% had received free condoms in last 6 months	667 patients who completed survey, 51% (339/667) of whom were self-identified gay men	53% completed course (n = 104). Mean age 37, 87% white, 59% degree or higher, 67% 'single'. 75% of course completers (n = 78) provided follow up data
<b>Comparison condition</b>	None	Pre & post comparison of random convenience samples from venues	None	None
<b>Description of the intervention:</b> (i.e. theory base, duration, facilitators, content & method of delivery)	Based on models of outreach and community mobilisation. This was a community instigated, volunteer-designed & -led intervention running for 6 months (May–Oct) each year. One paid project worker co-ordinated volunteer teams. Volunteers (3+/shift) provided condoms and safer sex materials at entry points & from 'glow boxes' within the PSE	Pilot assessment of effectiveness of free condom distribution in reducing levels of UAI due to lack of condom availability. Evaluation of distribution methods most likely to reduce pilfering and wastage and still make condoms readily available in gay venues	Strong visual image advertisements encouraging gay men to consider having an HIV testing in light of treatment advances – <i>"If you are positive, the sooner you know, the more you can do."</i>	Based on theories of assertiveness training. Intervention aimed to provide key assertiveness skills around choices, taking control & effective communication. Four 6hour sessions over two weekends. Course provided by trained facilitators using lecture, role-play & pairs exercises
<b>Main findings</b>	Outreach service was provided every night. More than 100,000 condoms distributed over 6 months. Safer sex, 'cruising safety' and drugs info packs valued by PSE users. Distributed condoms were used on the site	Comparison of pre- & post- data showed significant increase in proportion (%) receiving free condoms in last 6 months (76% vs. 83%); % reporting having condoms at home (83% vs. 73%); % carrying condoms (28% vs. 22%). However, no change in % reporting UAI due to poor condom availability (9.5% vs. 9.9%). Men attending focus groups believed giving out condoms reduced likelihood of UAI occurring	Of gay men attending the different sites, 79% had an HIV test on the day; 81% recalled campaign; 12.5% recalled the message correctly. However, only 9.3% said campaign had played a part in their decision to test	Course did not attract men known to be at highest risk of acquiring HIV (e.g. young gay men, men with regular partners). At 1 month follow up: completers attributed changes such as greater self-awareness and respect for personal rights to their having attended the course. At follow up, improved standardised assertiveness scale scores were greatest in those with the lowest baseline scores
<b>Conclusions</b>	Successive evaluations confirmed need for this outreach work. Volunteer-led peer intervention was appropriate & valued by volunteers & recipients alike. Volunteer input key element in its success. Condom availability a key health promotion need in the PSE setting	Increased condom access in gay venues was attributable to different distribution methods. Free provision did not effect the end use of condoms, had no impact on % having UAI. Scheme should continue even if unlikely to impact on % of men reporting UAI	Campaign had modest effect at individual level but was more important as a part of a general normative shift in attitudes towards HIV testing among all groups	Training had some effect for those who attended. Did not reach those with greatest HIV prevention need. Provided a safe & supportive environment. Being gay run & gay specific were key to acceptability. Increased targeting could improve efficiency of training provision

search involved elements of peer education or peer delivery. The reasons for this seems fairly clear, however what is not, is why they were more likely to have been evaluated (Hart 1998). Firstly, peer-led interventions had been shown to be effective by researchers in the United States (Kelly *et al.* 1992). Secondly, peer education reflected the established tradition of volunteer involvement in HIV prevention (King 1999). And thirdly, as proposed by Hart and Elford, peer education and peer delivery are the most intuitively attractive approaches to the prevention of communicable diseases (Elford *et al.* 2002a; Hart & Elford 2003). However, as their own research has demonstrated, they may not always be the easiest, most cost effective or successful methods (Elford *et al.* 2002a; Hart 1998; Hart & Elford 2003).

Expansion in the early 1990s was also characterised by interdisciplinary and professional collaboration between researchers, clinical providers and prevention workers. This was particularly the case in relation to development of so called 'complex interventions', that specifically sought to make a measurable impact on behaviour change (Elford *et al.* 1998; Elford *et al.* 1999a; Wanigaratne *et al.* 1997). It is interesting that most evaluation reports involved some researcher input (see Table 1), but in the case of those that met the criteria of methodological rigour (Table 2) they were almost always based on researcher/provider partnerships or researchers working on their own.

### *Health promotion models and approaches*

Gay men's HIV prevention also became more sophisticated in its use of different health promotion models. Health promotion theorists Naidoo and Wills have described effective health promotion as involving simultaneous deployment of interventions utilising five main approaches: medical, education, behaviour change, empowerment and social change (Naidoo & Wills 1994). Interventions based on each of these approaches were being used in HIV prevention with gay men during the 1990s. For example, Walsh and Wanigaratne's interventions were clinically-led and targeted men at increased risk of HIV exposure (Walsh



*et al.* 1997; Wanigaratne *et al.* 1997). All but one of the examples included some element of health education (Weatherburn 1997a). Three had explicit individual or community empowerment objectives (French *et al.* 2000; Hickson & Boxford 1999; Wanigaratne *et al.* 1997). There were also social change interventions which often involve community action, or legislative or social policy change (Bonell *et al.* 2003; Bonell & Imrie 2001; Easton & Klein 2000; Parker *et al.* 2000). Gay Men Fighting AIDS (GMFA) Hampstead Heath Project is an exemplar of the community-action approach (Burnell *et al.* 1995; French *et al.* 2000; French *et al.* 1998; Garfield 1994). Even though it did not directly involve policy or legislative initiatives, GMFA's Hampstead Heath Project, along with the 'Rubberstuffers' programme, demonstrate in concrete terms a move towards more 'healthy public policies' through social marketing and free distribution of condoms (World Health Organization 1986).

#### *The role of social and psychology theories*

As complex and multiple component behavioural interventions became more popular, theories of behaviour change became notable features of intervention design (Thornton & Catalan 1993). The main practical value of these theories was as a framework within which behaviour and behaviour change could be understood. In this way, theories could be equally useful in understanding a problem or in guiding aspects of the intervention response (King 1999). The varied use of theory reflects the eclectic and multi-disciplinary approaches to HIV prevention being employed. The theories most commonly associated with HIV prevention come from the social and social-psychological fields, although models from education, communication, marketing and organisational behaviour have all been used in various forms (DiClemente & Peterson 1994; King 1999; Nutbeam & Harris 1999; Sutton 2003).

Entire theories or selected components were used to design whole interventions or simply parts of them. Combining elements of different theories in the same intervention was also

common (Nutbeam & Harris 1999; Stephenson *et al.* 2000; Sutton 2003). For example, peer education and 'diffusion of innovation' were frequently used in combination (Elford *et al.* 2000b; Flowers *et al.* 2000a; Kelly *et al.* 1992; King 1999). Given the historical precedent of the relapse debate and the source documents used in this review, it is not surprising that nearly all the reports claimed behavioural change theory had in some way contributed to the interventions. But what is interesting, is that it was the same theories being used to inform interventions targeting UK gay men as elsewhere, with almost no variation or adaptation to the cultural differences (DiClemente & Peterson 1994; Hart 1997; Hart 1998; Kelly 2000; Kelly *et al.* 1989; King 1999; Nutbeam & Harris 1999; Oakley *et al.* 1996). Even so, it is not clear from the reports that claimed to have incorporated theory in their intervention design how this was done or if there was any empirical justification for the choice of theory (Stephenson *et al.* 2000; Sutton 2003).

The selected examples in Table 1 also show the different ways theory was used. For example, some interventions were guided by a single model (Hickson & Boxford 1999), while others used key concepts from more than one model in designing the intervention (Wanigaratne *et al.* 1997). A third approach was to use theory selectively to determine the intervention method or delivery approach, but without incorporating it into the actual intervention content. For example, elements of peer education, outreach and empowerment models informed printed safer sex education materials use in a PSE, but were not incorporated in the content of the materials (Dockrell *et al.* 1996; French *et al.* 1997). A fourth approach involved an even more pragmatic use of theory, that was to describe the delivery approach, but without actually incorporating any specific theory in the intervention (Deverell 1995; Shepherd *et al.* 1997).

#### *General and targeted interventions*

The selected examples in Tables 1 and 2 illustrate that gay men's HIV prevention involved a mix of generic and targeted interventions, although it seems that targeted interventions were

more likely to have been evaluated. This perhaps reflects arguments in the literature earlier on which called for more interventions that targeted identifiable sub-populations of gay men known to be at greater risk of HIV infection, for example young gay men, men attending sex-on-premises venues, men using GUM clinics (Hickson *et al.* 1994; Kwok 1997; Kwok 1998; Weatherburn *et al.* 2003; Weatherburn *et al.* 2001). Several reports describe using routine STI and HIV surveillance data or clinical audit as justification for their targeted interventions, while others claimed the programmes were driven by 'reviews of the literature' and consultations with experts (Bean *et al.* 1999; Deverell 1995; Shepherd *et al.* 1997; Wanigaratne *et al.* 1997). Tellingly, however, beyond this, it is not obvious how decisions to implement more focused interventions were reached. In one case the authors report that the decision to go forward with the intervention was based on the '...assumption that it [free distribution of condoms in commercial gay venues] was a valuable activity ... And a universal assumption that it must have an impact on the incidence of unprotected anal intercourse and hence the incidence of new HIV infections' (Weatherburn 1997a, p. 3). Overall, it seems that in the early 1990s there was very limited use of either formative research or needs assessment in decisions about which interventions should be implemented (Hart 1995; Hart 1998; Rossi *et al.* 1999). This seems to have changed later in the decade when needs assessment and repeated population surveys became the most common way of justifying existing programmes and the introduction of new ones (Annetts *et al.* 1996; Hickson *et al.* 1994; Hickson *et al.* 1996; Hickson *et al.* 1998; Hickson *et al.* 1999; Hickson *et al.* 2001; Hickson *et al.* 2002; Kelley *et al.* 1996; Keogh *et al.* 1997; Keogh *et al.* 1998; Reid *et al.* 2002; Scott 1996; Terrence Higgins Trust Policy, Research & Development Unit 1999).

### *Providers*

Ring-fenced funding facilitated expansion in the number of prevention providers but, with few exceptions, it did not translate into more published evaluations. Publication of evaluation appears to have remained confined to statutory health promotion, public health and academic

researchers. This in itself is not surprising. However, what is surprising is that in most cases these professionals were also the intervention providers or key players in the intervention development and delivery (Elford *et al.* 2000b; Flowers *et al.* 2000a; Wanigaratne *et al.* 1997; Williamson *et al.* 2001). The conclusion being that evaluation was not a significant part of practitioners' thinking in respect to HIV prevention.

### *Intervention settings*

The value of using different settings is encapsulated in the Ottawa Charter for Health Promotion – '... health is created and lived by people within settings of everyday life: where they learn, work, play and love' (World Health Organization 1986). In the early to mid 1990s, key UK Department of Health documents also recognised that using different settings offered the best opportunity of reaching the largest number of people with its health promotion messages (DoH 1992; DoH 1995). However, primarily because of social stigma, gay men's HIV prevention has almost always been delivered exclusively in carefully selected 'gay settings' like community groups, commercial gay venues and PSEs. Even interventions in clinical settings were only offered in clinics where significant numbers of gay men already attended, rather than using the intervention as a draw to attract new clients (Walsh *et al.* 1997; Wanigaratne *et al.* 1997). Only one of the selected examples, a media campaign promoting HIV testing, mounted posters in a general setting (the London Underground) (Sherr *et al.* 1999b) (Personal Communication: Dr Tony Nardone, Public Health Laboratory Service, June 2001).

### **3.8 Evaluation of HIV prevention targeting gay men**

The examples in Tables 1 and 2 illustrate how the mid to late 1990s were also characterised by a major shift of emphasis towards the design and conduct of more rigorous evaluations.

### *Evolution of evaluation*

The shift is reflected chronologically in the selected examples. As suggested in the previous chapter, this was partially driven by changes in commissioning and funding arrangements, and developments in the scientific community (Bonell 1995; Bonell & Devlin 1996; Hart 1995; Hart 1997; Keogh *et al.* 1997; Oakely 1990; Oakley *et al.* 1996; Oakley *et al.* 1995a). But by the late 1990s, nearly all evaluations included some attempt to link an intervention with a positive prevention effect, even if the evaluation was not specifically about effectiveness, for example, in the case of process and pilot evaluations (French *et al.* 2000; Wanigaratnes *et al.* 1997). Three of the selected interventions (see Tables 1 and 2) began prior to the start of this study, one in the same year (i.e. 1995), and the others between 1996 and 1998. Of those started before 1995, one was a process evaluation (Deverell 1995), two described themselves as 'pilot studies' (Wanigaratne *et al.* 1997; Weatherburn 1997a), and only one met the criteria of an outcome study (Walsh *et al.* 1997). By contrast, all but one of the selected examples that started after 1995 describe themselves as outcome evaluations, although not all of them met the essential criteria to be classified as such (Coyle *et al.* 1991; Oakley *et al.* 1996; Rossi *et al.* 1999).

### *Types of reported evaluations*

Each of the three main classes of evaluation – formative, process and outcome – are represented in the UK literature and the selected examples (see Tables 1 and 2) (Coyle *et al.* 1991). However, there were no reports of studies that explicitly referred to themselves as formative evaluations and there were no experimental evaluations reported in the UK literature prior to 1995 (Oakley *et al.* 1996).

Formative evaluation, as referred to earlier, is frequently linked to needs assessments. It attempts to identify the issues, goals and priorities in advance of an intervention being designed or implemented (Rossi *et al.* 1999). Process evaluation is mainly concerned with an

intervention in operation – how it is set up, delivered and received by the target audience – in short, what goes on rather than what effect it has (Wight & Obassi 2003). Outcome evaluations are intended to answer specific questions about what effect an intervention has on specified outcomes (Oakley *et al.* 1996; Peersman *et al.* 1996a; Rossi *et al.* 1999; Stephenson & Imrie 1998). Pilot studies bridge the gap between process and outcome evaluations, focusing on assessments of acceptability and feasibility and at the same time ensuring procedural safeguards are in place before the start of the main evaluation (Rossi *et al.* 1999; St Leger *et al.* 1992).

### *Formative research studies*

Formative research and needs assessment are essential steps in the development of complex health interventions (Campbell *et al.* 2000; Nazareth 2003; Rossi *et al.* 1999; St Leger *et al.* 1992; Stephenson *et al.* 2000). However, the link between formative research and the design and development of prevention interventions is often poorly explained in research reports (Bonell *et al.* 2003; O’Leary *et al.* 1997; Stephenson *et al.* 2000). In the early 1990s, UK prevention providers appear to have made almost no use of formal formative evaluation in developing their interventions (McKevitt *et al.* 1993). One explanation for this is that formative research or pre-testing of education materials would have been undertaken by the responsible advertising agencies and therefore would not have been published in the scientific literature (Health Education Authority 1993; Hickson *et al.* 1994; Kwok 1997). A second possible explanation is that given the uncertainty about the impact of media campaigns, pre-testing and formative research was not considered a good investment of limited financial resources (Garfield 1994). As one of the few evaluations of a novel education campaign concluded ‘... few men [involved in developing and pre-testing] felt the materials would have any effect on sexual behaviour...’ (Hickson *et al.* 1994). It appears that a widely held view was that first-hand knowledge of HIV’s devastating effects was enough to know what was needed without ‘indulging in luxury’ of formative research (Garfield 1994).

But this changed over the course of the decade. Renewed interest in formative research and needs assessment appears to have been partially motivated by published reviews of HIV prevention work, by development of local HIV prevention strategies, increased 'professionalisation' of the HIV prevention field and more decentralisation of both research and prevention purchasing (Aggleton 1994; Bonell 1999; Bonell & Devlin 1996; Hart 1995; Hart 1997; HIV Prevention Strategy Group 1993; Kelley *et al.* 1996; Keogh *et al.* 1997; Oakley *et al.* 1996; Rooney & Taylor 1997; Weatherburn *et al.* 1994; Weatherburn *et al.* 1997).

Several interventions identified in the literature claimed to have been developed based on needs assessment, but there is no mention of what the needs assessment findings were or how they were used to develop the intervention, only that they justified developing it (Gay Men Fighting AIDS 1994; Hickson *et al.* 1994; Kwok 1997). In the case of the selected examples in Tables 1 and 2, it is nearly impossible to determine whether any formative research was undertaken and, if so, whether and how it was incorporated into the intervention development.

#### *Pilot studies*

Results from pilot studies should not usually be considered as adequate evidence of effectiveness (Bowling 2002; O'Leary *et al.* 1997; Rossi *et al.* 1999). By definition the main purpose of pilot studies is to provide the preliminary indications in advance of a full-scale outcome evaluation of an intervention's effectiveness (Bowling 2002). But this does not seem to have been the case in relation to HIV prevention with UK gay men where pilot studies alone have been sufficient to justify continued provision of interventions without any further outcome evaluations. This was the case in respect to two of the selected examples described by the authors as pilot studies (Wanigaratne *et al.* 1997; Weatherburn 1997a). Although neither example could be described as a textbook pilot study, both did measure feasibility, acceptability and, to a lesser extent, efficiency. Weatherburn's study assessed

different approaches to free condom distribution to identify the optimal method to maximise availability, while limiting pilfering and wastage (Weatherburn 1997a). In contrast, Wanigaratne's pilot evaluation of the 'Changing personal sexual practice' intervention claimed to be mainly concerned with development of a broader evaluation framework. But the results reported are in a fashion more akin to an outcome evaluation than a pilot study. They focus on the effect of the intervention, on changes in attitudes and sexual behaviour, without any reference to feasibility and acceptability of the intervention or any process measures (Rossi *et al.* 1999; Wanigaratne *et al.* 1997). This might presumably have been because the authors felt acceptability and feasibility had already been demonstrated in a prior small-scale assessment several years earlier (Williams *et al.* 1993).

Neither pilot study could be said to have produced sufficiently robust evidence to support either intervention's indefinite continuation, particularly given the cost of providing them. Yet funding for both interventions continued for several more years without any formal outcome evaluation. In the case of 'Changing personal sexual practice', the intervention continued until 2000, when it was finally dropped because it failed to recruit sufficient participants (Personal Communication: Simon Paragreen, GUM Health Promotion Co-ordinator, Camden & Islington Health Promotion Service, November 2000). The Rubberstuffers programme also continued through 2000, when the contract was put out for tender and awarded to another agency which has substantially altered the programme with the ultimate aim of making it self-financing (GMFA 2000) (Personal Communication: Mark Maguire, HIV and Sexual Health Manager, Camden & Islington Health Promotion Service, May 2001).

### *Process evaluations*

Process evaluations, which provide essential information about what an intervention involves, how it is delivered to, and received by, the target audience appear to have been the strongest



area of UK evaluation work. For example, Deverell's 'KY Babies' evaluation demonstrated that the intervention team was able to establish, maintain and continue to attract new members to a group providing peer education training to young gay men (Deverell 1995). On the other hand, the Hampstead Heath Project involved a volunteer-led programme providing safer sex materials, primarily condoms, lubricant and educational information, in a PSE (Burnell *et al.* 1995; French *et al.* 1997; French *et al.* 2000). French *et al.*'s evaluation of the Hampstead Heath Project identified key factors that ensured the intervention was successfully delivered. They also established that the condoms provided were actually being used on the site (French *et al.* 1997; French *et al.* 2000). The findings of these two evaluations are important because they demonstrate another key function of process evaluations, that is making available the essential information necessary to successfully replicate an intervention in another setting (Wight & Obassi 2003).

However, like the case of the two pilot studies, these process evaluations appeared to have provided adequate evidence for them to continue to be funded without any formal outcome evaluation. Regrettably this theme continues up to today. Researchers who completed two recent HIV prevention activity maps in 1999/2000 and 2000/2001 concluded that all interventions that had been subject to *any* evaluation, and not just outcome evaluations, were worthy of continued financial support, so long as their aims prioritised the HIV prevention needs of gay men, based on the national framework document *Making it count* (Hartley *et al.* 1999; Hickson *et al.* 2000; Hickson *et al.* 2001).

### *Outcome evaluations*

Four of the selected examples in Table 1 attempted to assess the impact of specific interventions and classified themselves as outcome evaluations (Hickson & Boxford 1999; Shepherd *et al.* 1997; Sherr *et al.* 1999b; Walsh *et al.* 1997). Outcome evaluations aim to measure whether an intervention actually produces its intended effects and thereby, in some

way, reduces the likelihood of poor health outcomes (Downie *et al.* 1996; Naidoo & Wills 1994; St Leger *et al.* 1992). Health promotion researchers generally agree that determining whether a prevention intervention is effective cannot be done with certainty, but with only varying degrees of plausibility (Naidoo & Wills 1994). This is because the cause and effect relationship in health promotion is almost never clear-cut in the way it is, for example, in a surgical or pharmacological intervention (Bonell *et al.* 2003; Kippax 2003; Rossi *et al.* 1999; Stephenson *et al.* 2000). As a consequence, the design of outcome evaluations is essential to producing the best possible evidence of efficacy and effectiveness – the more rigorous the evaluation design, the more convincingly it can be argued the results are attributable to the intervention (Rossi *et al.* 1999; St Leger *et al.* 1992). The same principles apply in respect to which outcome measures are used in the evaluation (Cowan & Plummer 2003).

In the mid 1990s, the most rigorous evaluations to be found in the UK literature were either retrospective designs with carefully defined or matched controls or prospective designs with undefined or no control groups (Shepherd *et al.* 1997; Sherr *et al.* 1999b; Walsh *et al.* 1997; Wanigaratne *et al.* 1997). Several evaluations did use pre- and post-intervention surveys in the same target populations, while others used only follow up surveys (Shepherd *et al.* 1997, Weatherburn 1997a). Based on the search results, only one evaluation started prior to 1995 could be described as having used a genuinely appropriate comparison group (Walsh *et al.* 1997). Interventions, such as this one by Walsh *et al.* that were undertaken by clinic-based researchers were more likely to use more robust methodologies than evaluations undertaken by community HIV prevention providers (Hart 1996b). Clinical service interventions were also the only evaluations that used objectively determined outcome measures. For example, in Walsh *et al.*'s case, 'first time attendance for male patients' was the main outcome based on a review of the clinic's databases (Walsh *et al.* 1997). The fact that more robust evaluations appear to have been undertaken in clinical and service settings is important because it reflects the public health and health services agendas driving developments in the

research community, while a softer health promotion agenda held sway among community providers (Hart 1996b). It is also likely that, because many of the investigators in the clinic and service based studies already possessed essential evaluation skills, they were better equipped to demonstrate an intervention effect using more convincing outcome data. Prior to 1995, no UK evaluations employed the most rigorous evaluation designs, that is randomised controlled or quasi-experimental evaluations (Oakley *et al.* 1996).

Evaluations of health education interventions were the least likely to be reported in the scientific or 'grey' literature. This may have been because, as some have argued, these types of interventions are by their very nature unsuitable for rigorous evaluations (Keogh 2001; Kippax 2003; Kippax & van de Ven 1998; Weatherburn *et al.* 2001). But more recently, both mass media and health education interventions have been subject to carefully designed evaluations, using quasi-experimental evaluations with robust endpoints, for example the proportions in the population either 'HIV tested in the last year' or 'vaccinated against Hepatitis A and B' (McOwan *et al.* 2002; McOwan & Lindan 2001; Reaney 2000; Weatherburn *et al.* 2001; Weatherburn *et al.* 2003).

Given the skills, financial resources and other complexities involved in delivering intensive face-to-face interventions it is surprising that so few of these have been rigorously evaluated (Kelly 2000). In the few examples where they were, study design issues and outcomes make it impossible to draw safe conclusions about the interventions' actual effectiveness (see for example: Foskett & Hurst 1996). The two examples of outcome evaluations of complex face-to-face interventions in Table 1 both began after 1995. These examples are interesting because they demonstrate some of the specific difficulties of rigorously evaluating interventions outside of carefully designed RCTs (Hickson & Boxford 1999; Shepherd *et al.* 1997).

Hickson and Boxford's 'Assert Yourself' evaluation also illustrates an important development in respect to the choice of outcomes because its primary outcomes measures were explicitly linked to the intervention's theoretical base (Heimberg *et al.* 1977; Hickson & Boxford 1999; Rathus 1973). The main evaluation outcomes focused on measures of assertiveness and testimonial evidence from intervention completers (Rathus 1973). However, the lack of a control group, the exceedingly short follow up period and the small self-selected follow up sample, make it difficult to conclude whether the intervention would be effective in any other population of gay men (Hickson & Boxford 1999).

### **3.9 Methodologically rigorous evaluations**

This section discusses the five evaluations identified in the search that met at least some of the criteria of rigorous and methodologically sound evaluations (see Figure 2) (Dockrell J *et al.* 1999; Dockrell M 1999; Elford *et al.* 2000b; Elford *et al.* 2001; Flowers *et al.* 2002; Flowers *et al.* 2000b; Golombok *et al.* 2001; Shepherd *et al.* 1997; Williamson *et al.* 2001). All of the experimental evaluations identified in the search started either in the same year or in the years after the instigation of the study described in this dissertation (see Table 2). They all conform, in varying degrees, to Oakley *et al.* and/or the CDC's Prevention Research Synthesis Project's criteria for *methodological soundness* or *rigorous evaluations* (see Figure 2), but none could be genuinely described as an individually randomised controlled trial of a behavioural intervention. However, they are still extremely important, because they illustrate the remarkable shift in HIV prevention evaluation thinking that occurred in the second half of the 1990s (Hart 1995; hart 1996a; Hart 1996b), and they are part of the research context of this study.

Despite moves towards more methodologically rigorous evaluations, only six UK reports were identified in the literature search that claimed to be either experimental or

**Table 2:** Reports of UK gay men's HIV prevention intervention evaluations described by authors as 'rigorous or methodologically sound'

<b>PROJECT NAME</b>	<b>'Hard Times'</b>	<b>'Gay Men's Task Force'</b>	<b>'4 gym project'</b>	<b>Thicker vs. Standard Condoms for Anal Intercourse (AI)</b>
<b>Main intervention</b>	Small group, cognitive behavioural workshop	Interagency collaboration to provide peer education, a telephone help-line & dedicated STD clinic services	Community peer education project in central London gyms	Double-blind RCT head-to-head comparison of standard vs. strong condoms use for anal intercourse.
<b>Implementing &amp; evaluating agencies</b>	Gay Men Fighting AIDS (GMFA) & Institute of Education, University of London	MRC Social and Public Health Sciences Unit, University of Glasgow & Glasgow Health Board	Royal Free & University College Medical School & Camden and Islington Health Promotion Service	City University, London
<b>Published references</b>	Burnell 2000; Corrigan & Harding 1999; Dockrell J <i>et al.</i> 1999; Dockrell M 1999; GMFA 1998; Harding 1999	Flowers <i>et al.</i> 1998a; Flowers <i>et al.</i> 1998b; Flowers <i>et al.</i> 1999a; Flowers <i>et al.</i> 2000a; Flowers <i>et al.</i> 2002; Frankis & Flowers 1999a; Frankis <i>et al.</i> 1999b; Hart 2004; Hart & Elford 2003; Williamson <i>et al.</i> 2001	Bolding 2000; Bolding <i>et al.</i> 2002; Bolding <i>et al.</i> 1998; Bolding <i>et al.</i> 1999; Elford 1999; Elford 2004; Elford <i>et al.</i> 1998; Elford <i>et al.</i> 1999a; Elford <i>et al.</i> 1999b; Elford <i>et al.</i> 1999c; Elford <i>et al.</i> 2000a; Elford <i>et al.</i> 2000b; Elford <i>et al.</i> 2001a; Elford <i>et al.</i> 2001b; Elford <i>et al.</i> 2002b; Hart & Elford 2003	Golombok <i>et al.</i> 2001; Harding 2000; Harding <i>et al.</i> 1999
<b>Duration of project</b>	1996–2000	October 1997–June 1998	September 1997–March 1999	1998–1999
<b>Evaluation design</b>	RCT to investigate impact of 3 different intervention conditions: 1) Structured group-work (12 hrs over 6 weeks); 2) Self-help guide/workbook only (same as one given out in group work, and 3) Waiting-list control group	Quasi-experimental two-city comparison study (Glasgow & Edinburgh). Qualitative investigations of local sexual cultures used to design intervention and process measures. Cross-sectional community surveys at baseline & follow up measured intervention effects (Glasgow) and temporal effects (Edinburgh)	Controlled trial with staged introduction of intervention in 4 gyms; fifth served as control. Follow up at 6, 12 and 18 months. Booster session (i.e. re-introduction of intervention in 1 gym after 12 months). Attitudes and behavioural outcomes relating to sexual behaviour and steroid injecting patterns	Randomised double-blind controlled head-to-head comparison of a 'thicker' vs. standard condoms for use in AI by gay men
<b>Intervention goals</b>	Encourage engagement in personal review & reflection and eventual development of personal sexual risk reduction strategy	Improve gay community's sexual health through provision of appropriate community services and reduce sexual risk behaviour through peer education	Reduce levels of status-unknown UAI & needle/syringe sharing for steroids injecting. Increase knowledge of new HIV treatments. Increase uptake of HIV testing	Measure condom failure in gay men users depending on type of condom-used. Increase condom choice options. Improve safer sex advice through understanding of factors associated with condom failure

<b>PROJECT NAME</b>	<b>'Hard Times'</b>	<b>'Gay Men's Task Force'</b>	<b>'4 gym project'</b>	<b>Thicker vs. Standard Condoms for Anal Intercourse (AI)</b>
<b>Setting</b>	Community venues including gay bars and community centres	Community venues and clinic-based facilities	5 gyms in central London	Community-based study
<b>Intervention population (N = ).</b>	N = 62 split into 3 arms. No data on numbers in each arm, no trial flow data provided. At baseline, 63% of groupwork, 67% of print intervention and 75% of control participants reported having taking an 'unwanted sexual risk' in previous 8 weeks	Gay men attending venues in Glasgow. Baseline survey (N = 2276; Glasgow 1245, Edinburgh 1031) In-depth interviews (n = 38; Glasgow 20, Edinburgh 18). 42 men completed PE training	Gay gym users. Repeated cross-sectional surveys at baseline, 6, 12 & 18 months. Proportion reporting status-unknown UAI at baseline = 14%; currently injecting steroids 8%; no needle/syringe sharing reported	Couples either not using condoms or not using strong condoms for AI (N = 356) (completers = 283. Allocation: 141 standard vs. 142 strong). 50% resident in London. Mean age = 33; 92.7% white; 52% educated beyond secondary school
<b>Comparison condition</b>	Waiting list control group. (After 8 weeks, given intervention of choice)	Baseline & follow up surveys in control city to look for temporal trends	Baseline & follow up surveys in intervention gyms and in control gym for temporal trends	Head-to-head comparison of commercially available products
<b>Description of the intervention:</b> (i.e. theory base, duration, facilitators, content & method of delivery)	Intervention based on cognitive behavioural approaches to counselling. <i>Groupwork:</i> structured course, once a week for 6 weeks facilitated by experienced professionals. Workbook guide was given to the groupwork participants. <i>Workbook:</i> short, interactive, self-help guide for use on its own or with a Health Advisor.	Intervention – Based on 'diffusion of innovation' theory. Gay Men's Task Force included bar-based, peer-led sexual health promotion, gay-specific GUM services in both hospital & community settings; free-phone help-line	Based on 'diffusion of innovation' theory: popular men in each gym invited to become PEs. 63 potential PEs approached in different gyms & 19 completed training; 17 served in project. PEs asked to conduct 20–25 education sessions with persons at gym. Phased introduction in 4 gyms, 1 got additional 'booster' after 12 months. Fifth gym served as control	Attempt to validate or refute current safer sex advice recommending strong condoms for AI. Couples allocated 9 of either condom type. Baseline survey and questionnaire following use of each condom
<b>Main findings</b>	Both interventions effective in changing attitudes associated with risk-taking. 83% of groupwork, 38.5% of workbook and 58% of controls reported no unwanted sexual risk-taking at 8 weeks follow up	42 PEs recorded 1484 intervention contacts. Attendance at sexual health service = 506. Main indices: non-significant reductions in reported UAI with casual partners, increased knowledge of own and partner's HIV status among those reporting UAI; significant increase in Hep B vaccination uptake	Little variation in proportion reporting status unknown UAI at 18 month follow up (13.9% vs. 14.2%). % ever testing for HIV increased in intervention and control gyms. % reporting injecting steroids increased but needle sharing remained very low	No significant differences found between condom types with respect to breakage or slippage. User demographic characteristics associated with failure: lower education attainment, lower confidence in condom-use, history of breakage, inappropriate use of lubricant & duration of AI session

<i>PROJECT NAME</i>	<b>'Hard Times'</b>	<b>'Gay Men's Task Force'</b>	<b>'4 gym project'</b>	<b>Thicker vs. Standard Condoms for Anal Intercourse (AI)</b>
<b>Conclusions</b>	Both interventions effective in changing attitudes towards risk-taking. Completing the detailed baseline interview contributed to reported risk reduction among controls. With adequate resources, community organisations can execute an RCT	PEs in community increased attendances at dedicated GUM service but ineffective in producing any education effect. PEs encountered difficulties in their dual roles of bar patrons and 'health promoters'. Gay bars are appropriate venues to conduct peer-led sexual health promotion	Peer education had no significant impact of HIV risk behaviours of men attending London gyms. Main problem was that the intervention was not delivered by the PEs. Models of HIV prevention effective in one setting may not necessarily be directly transferable to others	No evidence to support continued recommendation of stronger (thicker) condoms over standard for gay men for anal sex. Appropriate use of lubricant should be encouraged

quasi-experimental in design. One study by Shepherd is described in Table 1 (Shepherd *et al.* 1997), the other four are described in Table 2 and the sixth did not achieve a sufficient follow up (33%) to be considered as a useful example (Elford 1999). Of the examples that are included in the tables, two explicitly claimed to be RCTs (Dockrell J *et al.* 1999; Golombok *et al.* 2001), one referred to itself as a controlled trial (Elford *et al.* 2001b) and the other two were quasi-experimental evaluations (Flowers *et al.* 2002; Shepherd *et al.* 1997).

### *Key characteristics of methodologically rigorous evaluations*

The characteristics, merits and disadvantages of experimental evaluations and RCTs of behavioural interventions have all been discussed at length in the literature, so only the key issues are revisited here (Alderson *et al.* 1996; Bonell *et al.* 2003; Oakley 1990; Ross & Wight 2003; Stephenson 2003; Stephenson & Imrie 1998; Stephenson, Imrie & Bonell 2003;). The two main advantages of experimental evaluations in respect to sexual health interventions are: 1) inclusion of a control group that receives only the current standard care who are compared to the intervention group that receives intervention being evaluated (Bonell *et al.* 2003; Stephenson & Imrie 1998); and 2) comparison of measures between the experimental and the control groups at the post-intervention follow up (Ross & Wight 2003; Stephenson & Imrie 1998).

Not all experimental evaluation designs are equally robust however, and simply including a control group does not automatically guarantee that differences between groups are attributable to an intervention ( Bonell *et al.* 2003; Stephenson & Imrie 1998). Observed differences or associations at follow up may reflect other factors affecting participants or biased data collection which cannot be controlled for in the analysis unless enough participants are involved (sample size) (Bonell *et al.* 2003; Stephenson & Imrie 1998). Rigour is best obtained by attempting to ensure that the two groups are as similar in composition as possible in relation to factors, known and unknown, that are likely to affect



any outcome measures (Bonell *et al.* 2003; Bonell & Imrie 2001; Ross & Wight 2003; Stephenson & Imrie 1998). This is most effectively achieved through random allocation of participants (Bonell *et al.* 2003; Oakley 1990; Pocock 1983; Stephenson & Imrie 1998). Random allocation is preferable to other approaches. For example, while matching intervention and control participants can achieve the same objective, it is rarely possible to know about all the factors that may influence the effects of an intervention (Bonell *et al.* 2003; Pocock 1983; Stephenson & Imrie 1998). The additional rigour provided by randomisation is based on the premise that random allocation of sufficient participants to each group will result in groups that are similar in composition in respect to all factors that may influence the outcomes (Stephenson & Imrie 1998). This leaves the only key difference between them, being whether or not they received the intervention (Oakley *et al.* 1995; Ross & Wight 2003; Stephenson & Imrie 1998).

While these evaluation design attributes help ensure that the results of experimental evaluations are valid, it is the outcome measures that will be key in deciding an intervention's effectiveness (Cowan and Plummer 2003). It is the aims of an intervention that indicate what it seeks to achieve, and the outcome measures that provide the basis for determining whether it does this (Bonell 1995; St Leger *et al.* 1992). Most HIV prevention interventions aim to prevent or at least reduce HIV transmission and/or the negative sequelae of HIV infection. Therefore, ideally, incident HIV infections would be the most suitable ('gold standard') outcome measure in an experimental evaluation. But this is usually impossible because of the relatively low prevalence in most developed countries and the very large samples and lengthy follow up that are required (see, for example, Koblin *et al.* 2003). Consequently, proxy measures, either behavioural or biological, that can be linked to the likelihood or risk of HIV transmission offer 'a second best alternative' primary outcome for HIV prevention intervention trials (Aral & Peterman 1996; Aral & Peterman 1998; Bonell *et al.* 2003; Cowan & Plummer 2003; Peterman *et al.* 2000; Stephenson *et al.* 2000). Most often these are self-

reported sexual behaviours, although it is now widely accepted that biological or other objective endpoints provide a better standard for determining effectiveness (Aral & Peterman 1998; Johnson *et al.* 2003; Peterman *et al.* 2000; Stephenson *et al.* 2000; Stephenson & Imrie 1998). This is because biological outcomes are less likely to be subject to various types of reporting bias (Hennekens & Buring 1987). Uptake of services or routine clinical measures are also useful and less likely to be subject to bias, but sometimes they may not be appropriate because of their distal relationship to the actual intervention aims. For example, in the case of an intervention that aims to reduce HIV risk through changing individuals' sexual behaviour, measuring uptake of other prevention services or clinic attendance is not sufficiently proximal to the intervention's actual aims for it to provide a direct indication of the intervention's success or failure (Stephenson *et al.* 2000).

There is fairly wide agreement now, that despite their limitations, changes in incident STI, particularly infections suggestive of penetrative intercourse or non-condom-use, are the best biological indicator of changes in safer sex behaviour, and therefore, the effectiveness of a behavioural intervention (Aral & Peterman 1998; Cowan & Plummer 2003; Johnson *et al.* 2003; Stephenson *et al.* 2000). This is a relatively new development, and therefore it is not surprising that none of the selected examples incorporated incident infections or other biological indicators as an outcome measure. However, studies with a GUM clinic link or where access to routine clinical data is easier have included objectively measured clinical outcomes or have incorporated routine clinic data as an outcome measure (Flowers *et al.* 2002; Walsh *et al.* 1997; Williamson *et al.* 2001).

#### *Critique of UK experimental evaluations*

The peer-led intervention in Southampton reported by Shepherd *et al.* was evaluated using a so-called 'quasi-experimental and process evaluation design' (see Table 1) (Shepherd *et al.* 1997). The aim of the HAPEER Project was to train PEs to deliver sexual health promotion

education to other young gay men in social settings. The choice of behavioural outcomes was appropriate to the intervention and evaluation type, but there are two main problems with this evaluation. The first is the choice of comparison group and, the second, the timing of the baseline and follow up surveys. The choice of comparison group was a serious deficiency because the neighbouring community chosen (Bournemouth) was not in fact very similar or sufficiently independent. Moreover there is significant movement of men between the 'gay scenes' in the two towns, and therefore it was not possible to restrict or measure the likelihood of intervention 'leakage' into the comparison community (Bonell *et al.* 2003). The second and more important problem with this evaluation was that the baseline survey in the comparison community (Bournemouth) was undertaken after the intervention had started in Southampton. Consequently no genuine pre-intervention data was available for the control site. Given the likelihood of intervention leakage, it is not possible to measure the true effect of the intervention in Southampton based on a comparison with Bournemouth.

GMFA's 'Hard Times' evaluation is important because it is the only example of an intervention and evaluation developed, designed and executed by a voluntary sector organisation with limited external academic support (see Table 2) (Corrigan & Harding 1999; Dockrell J *et al.* 1999; Harding 1999). Although the authors describe their evaluation as a 'randomised control trial of a cognitive behavioural intervention' (sic), there are weaknesses in the study design and reporting that mean that this was an inappropriate description.

GMFA's evaluation involved comparing two different approaches to the delivery of a cognitive behavioural intervention and included a control group. The first intervention involved 12 hours of professionally delivered structured groupwork over six weeks. The second was a printed self-completion workbook, while the third (control condition) was an intervention waiting list that provided data twice before they received the intervention of

their choice (Dockrell J *et al.* 1999; GMFA 1998). The evaluators claim both interventions were based on cognitive-behavioural theory and involved groupwork, but only the first approach involved trained group facilitators.

Although the 'Hard Times' evaluation was an RCT in name, its design did not include important features of a genuine RCT, nor did the investigators report on key aspects of the trial design or its findings (CDC 1999; Moher *et al.* 2001; O'Leary *et al.* 1997; Oakley *et al.* 1996). For example, there was no report of the method of randomisation, the numbers allocated to each condition or of participant movement through the different stages of the trial (trial flow) (Moher *et al.* 2001). There was no description of whether the three groups were similar in composition at baseline or follow up, and the description of the intervention was insufficient for it to be replicated in another setting (National Institutes of Health 1997). The choice of primary outcome measure was not linked to the intervention's theoretical foundation or a direct measure of risk reduction. Instead, it reflected GMFA's own philosophy of individual empowerment in respect to sexual risk taking (i.e. 'the sex I have had in the last 8 weeks ... is as safe as I want it to be', 'safe enough for me') (Dockrell J *et al.* 1999; Dockrell M 1999; Gold 1995; Gold 1993; Gold & Skinner 1993a). While this outcome can be linked to GMFA's individual empowerment values, it does not provide a genuine indication of whether the intervention resulted in any actual behavioural change or re-enforced participants' pre-existing behaviours (Imrie *et al.* 1999; Imrie *et al.* 2001; Johnson *et al.* 2003). Analysis of the main outcomes was also inadequately explained with no indication of whether any adjustments were made for systematic differences between groups at baseline or follow up. Finally, the waiting-list control group was not treated as a genuine comparison group, in that all of the men received the intervention of their choice after completing a second survey at 8 weeks. Therefore there was no comparison group at all for the genuine intervention participants who also completed a final follow up questionnaire at 14 weeks post-intervention.

In contrast to GMFA's voluntary sector-led evaluation, the Gay Men's Task Force and '4 gym project' were both initiated and led by academic researchers, working collaboratively with community and statutory agencies (Elford *et al.* 2000b; Elford *et al.* 2002b; Flowers *et al.* 2000a). In each case the evaluation design met Oakley *et al.*'s and the CDC's Research Synthesis Project's essential criteria for rigorous evaluations (see Figure 2). In each study the investigators aimed to validate the use of peer-led interventions by replicating the success of American researchers using peer-education interventions based on diffusion of innovation theory (Kelly *et al.* 1992; Kelly *et al.* 1997; Rogers 1983; Rogers 2000). In addition, the Gay Men's Task Force drew on principles of individual and community empowerment by using peer support and community development approaches along the lines of those employed by Kegeles and colleagues in their 'Mpowerment Project' (Kegeles *et al.* 1996; Kegeles *et al.* 1999).

In respect to its methodology, the Gay Men's Task Force evaluation was a quasi-experimental two-city comparison study of community-based interventions undertaken in Glasgow, and Edinburgh served as the control. The 4 gym project was a controlled trial of peer education undertaken in 5 central London gyms and fitness centres, with either exclusively gay or predominantly gay membership; the fifth gym served as the control site to measure temporal trends.

The Gay Men's Task Force intervention aimed to improve the sexual health of Glasgow's gay community through provision of three intervention components: 1) bar-based peer-led sexual health promotion; 2) dedicated 'gay-friendly' GUM services in both hospital and community settings; and 3) a freephone information/counselling helpline (Flowers *et al.* 2002). The 4 gym project's primary aim was to reduce self-reported sexual risk behaviour and needle sharing for injecting anabolic steroids among gym users. The intervention consisted of training regular gym-users in basic HIV prevention and safer injecting, and then

supporting them to act as peer educators with others using the same facility (Elford *et al.* 1998; Elford *et al.* 1999b; Elford *et al.* 2000).

The Gay Men's Task Force intervention was provided in addition to the routine sexual health and HIV prevention services over a nine-month period from October 1997 to June 1998. Measurement of the main outcomes was based on repeated cross-sectional surveys in the two cities in 1996 prior to implementation (baseline) and then in 1999 and 2001 (follow up) (Flowers *et al.* 2002). The main outcomes included objective clinical measures: for example, the proportions in each city vaccinated against Hepatitis B, and self-reported behavioural measures including knowledge of own HIV status based on having had a test, UAI with different types of partners and 'negotiated safety' agreements with regular partners (Flowers *et al.* 2002; Kippax *et al.* 1993).

The 4 gym project evaluation also used cross-sectional surveys at each site to establish the baseline measures and then followed up with six-monthly surveys through the end of 1999. Peer education was introduced at each intervention site in succession over six-month periods in three phases. The first site to receive the intervention also received a 'booster dose' of intervention after one year (Elford *et al.* 1999b; Elford *et al.* 2002b). Unlike the Gay Men's Task Force, this evaluation did not report any objectively measured outcomes, relying exclusively on participants' self-reports. The main behavioural outcome measures were UAI with a partner of unknown or discordant HIV status, changes in reported HIV testing, needle sharing among steroid injectors and knowledge in relation to sharing of injecting equipment (Elford *et al.* 2001b).

The range of outcomes used in these studies meant it was possible to compile comprehensive pictures of the impact of each intervention in respect to the original study aims. For example, Flowers *et al.* observed significant increases in self-reported uptake of Hepatitis B

vaccination and HIV testing, specifically among those who had contact with a PE (Flowers *et al.* 2002; Flowers *et al.* 2000a; Williamson *et al.* 2001). They also noted substantial increases in attendance at the local gay specific GUM services (Flowers *et al.* 2000a). However, both studies had remarkably similar results in relation to their main behavioural outcomes, which suggested that neither intervention had a significant effect on sexual risk behaviour or uptake of HIV testing in the case of the 4 gym project (Elford *et al.* 2001b; Flowers *et al.* 2002; Hart & Elford 2003).

It was through the extensive process evaluations incorporated in each study, that the investigators were able to determine specific factors that influenced these results (Elford 2004; Flowers *et al.* 1999a; Hart 2004; Hart & Elford 2003; Williamson *et al.* 2001). In each case the process evaluations concluded that recruitment and retention of peer educators was difficult, and that there were significant communications barriers in the intervention settings that impeded delivery of the education messages (Elford 2004; Hart 2004). And both teams reached similar conclusions about why their interventions failed to deliver. As the report of the London evaluation concludes, 'Rather than peer education not working in London, it simply didn't happen' (Elford *et al.* 2002a. p.159).

In contrast, Golombok *et al.*'s trial of thicker vs. standard condoms is a much more conventional RCT that involved a head-to-head comparison of thicker and standard condoms in relation to their likelihood of failure (defined as slipping off or breaking) (Golombok *et al.* 2001). Unlike the other examples, this evaluation assessed different types of condoms and therefore relied on participants' self-reported 'normal sexual behaviours' to establish the different products' effectiveness relative to each other. Participants received one or other type of condom in random order, and were followed up immediately after they used all of them. This design made it easier to maintain the integrity of the trial, high participant follow up and reduce the likelihood of differential dropout rates between the two arms (Rossi *et*

*al.* 1999; Pocock 1983). The evaluators measured participants' demographic, physical characteristics and condom-use practices to identify behavioural factors associated with condom failure, which was the main trial outcome (Golombok *et al.* 2001).

Golombok *et al.* found there was no significant difference in the failure rate between the two types of condoms when used correctly. However, there were differences in user characteristics and in the behaviours of those who experienced condom breakage and slippage and those who did not. The significant factors associated with condom failure, using either type, were physical (penis size) and demographic characteristics (ethnicity and educational attainment) and several behavioural variables (duration of intercourse, use of insufficient or inappropriate lubricant) (Golombok *et al.* 2001).

A notable achievement in this trial is that the evaluators managed to 'blind' both researchers and participants to which type of condoms participants received. The benefits of 'double-blinding' – that is masking both researcher and participants to which intervention is received – are well described in the literature, but regrettably it is often impossible to achieve any blinding in trials of behavioural interventions (Pocock 1983; Stephenson & Imrie 1998).

Golombok *et al.*'s study, undertaken in 1998, was the only genuinely RCT with gay men undertaken in the UK to meet all of Oakley *et al.* and the CDC's criteria for rigorous and methodologically sound evaluation (CDC 1999; Oakley *et al.* 1996). It is an important contribution to the prevention literature but, because it was not a behavioural intervention trial, it cannot be treated in the same ways as the other example studies. The aim of Golombok *et al.*'s trial was to challenge what had up to this point been the received wisdom about which condoms should be recommended to gay men for anal intercourse (Golombok *et al.* 2001). The trial did not involve development or assessment of a new intervention that aimed to alter behaviour, and therefore did not struggle with the extra difficulties of



measuring individual behaviour change attributable to an intervention. However, the trial was successful in bringing about significant policy shifts in decisions about which condoms were made freely available by both GUM clinics and, after considerably more debate, health promotion services (Personal Communication: Will Huxter, GUM/HIV Services Commissioner, Camden and Islington Health Authority, May 2002).

### **3.10 HIV prevention targeting gay men in the UK in the 1990s**

By the late 1990s HIV prevention targeting gay men had become an established feature of the UK health promotion landscape. It had evolved rapidly during the decade, responding to changes in the political, funding, health service and research contexts. There was greater statutory and voluntary sector involvement and at the national level the Health Education Authority (HEA), came to play more of a co-ordinating role (Berridge 1996). With the dismantling of the HEA, this role was assumed by the Terrence Higgins Trust (a voluntary sector agency) within the context of a regularly updated national strategic framework – *Making it count* (Hickson *et al.* 1998; Hickson *et al.* 2000). GUM clinics increased their role and became a focal point for primary prevention through provision of innovative services, counselling and education interventions (Hartley *et al.* 1999; Keogh *et al.* 1997; London Gay Men's HIV Prevention Partnership 2003; Weatherburn *et al.* 1997).

The content of HIV prevention interventions was diversified and extended. Print media and health education campaigns remained the cornerstone, but the content and delivery evolved substantially (Deverell & Rooney 1994; Weatherburn *et al.* 2001). More resources were directed towards intensive one-to-one interventions, either peer-led or professionally delivered. Structural and social interventions targeting gay men in social situations and venues also became features of the commercial and non-commercial gay scenes (Bean *et al.* 1999; North and Mid Hampshire Health Authority 1999; Weatherburn *et al.* 1994; Weatherburn *et al.* 1996; Weatherburn 1997a; Whittaker *et al.* 1996). Interventions became

more sophisticated partly because providers were exposed to more international research and worked with greater autonomy at the local decision-making level (Billington *et al.* 1995; Deverell & Rooney 1994; McOwan *et al.* 2002; Wanigaratne *et al.* 1997). Research that demonstrated how some gay men adapted their safer sex practices in different situations, and the realisation that not all gay men were at the same level of HIV risk, led to greater attention and resources being focused on specific sub-populations (Elford *et al.* 1999a; Elford *et al.* 2001a; Henderson *et al.* 2001; Imrie *et al.* 1999; Keogh *et al.* 2000; Keogh *et al.* 1998; Weatherburn *et al.* 1996). Theory and needs assessment began to replace intimate experience as the main determinant of which interventions were needed, and how they should be developed and delivered (Keogh *et al.* 1998; Scott 1996). Interventions also began to target the intermediate prevention steps and broader issues affecting gay men's health (Hickson *et al.* 1994b; Hickson & Boxford 1999; MESMAC Yorkshire 1994).

But while HIV prevention became more sophisticated and extended its reach, the evaluation evidence base supporting activities lagged behind (Ellis *et al.* 2003). Prior to 1995, most evaluation was unpublished or produced exclusively for funders. It focused on monitoring and implementation, and was unable to demonstrate in a public health sense that it was reducing the likelihood of new HIV infections occurring (Bonell 1995; McKevitt *et al.* 1993). The convergence of the factors that brought about the shift in funders and researchers' attitudes towards evaluation is clearly marked in the published literature. But evidence of effectiveness concerning locally provided interventions continues to be extremely limited, even today. Yet even after the set-up and completion of several rigorous studies, including this one, evaluation remains, in the minds of many prevention providers, a secondary activity for which they received no additional funding (Bonell 1999; Ellis *et al.* 2003). In the late 1990s, when funders and purchasers insisted that HIV prevention intervention providers undertake evaluation and engage in reflective practice, most considered it to be a control

mechanism and a potential means to remove or reduce funding rather than something that would benefit their own work or wider prevention services (Bonell 1999).

A notable positive feature of this otherwise dismal picture has to be the part played by academic researchers. Working collaboratively with statutory and voluntary sector providers, academic researchers have made significant contributions to our understanding of what works and how. In the mid 1990s funders and policy-makers articulated a commitment to improving the evidence base through the setting up of RCTs of interventions. However, at the time this study was instigated, none had been initiated. This then is the context in which the trial described here must be considered. As the first individually randomised controlled trial of behavioural intervention with the aim of reducing risk of HIV transmission in gay men, its potential contribution to both the evidence base and prevention planning was significant. It also had significant potential as a demonstration project, showing an otherwise sceptical audience of purchasers and practitioners the value of carefully conceived rigorous experimental evaluations.

## **Chapter 4**

### **Evolution and development of the intervention**

#### **4.0 Introduction**

This chapter describes the evolution and development of the intervention evaluated in the RCT. Known as the 'BIG Project Workshop' (Behavioural Intervention in Gay men), it drew extensively on one of the interventions described in the previous chapter — 'Changing personal sexual practice' (Wanigaratne *et al.* 1997). 'Changing personal sexual practice' was conceived, developed and implemented by a multi-disciplinary team including a clinical psychologist, health advisors/counsellors and social workers based within the NHS sexual health services of Camden and Islington Health Authority (Billington & Wanigaratne 2000). The aims of 'Changing personal sexual practice' were to reduce HIV and STI risk by facilitating sexual behaviour change, increasing awareness, improving self-confidence in sexual situations and providing accurate information about HIV and STI (Billington & Wanigaratne 2000; Wanigaratne *et al.* 1992). The original 'Changing personal sexual practice' team have disseminated descriptions of the intervention's development and

evaluation elsewhere (Billington *et al.* 1997; Billington & Wanigaratne 2000; Rodgers *et al.* 1997; Wanigaratne *et al.* 1992; Wanigaratne *et al.* 1996; Wanigaratne *et al.* 1997; Williams *et al.* 1993).

The chapter has four aims:

1. To describe the rationale for developing and evaluating a small group behavioural intervention for gay men.
2. To summarise the theoretical base, content and experience of delivering the 'Changing personal sexual practice' intervention.
3. To explain how 'Changing personal sexual practice' was re-formulated into the BIG Project Workshop, illustrating how in this format it was an appropriate candidate intervention for an RCT evaluation.
4. To describe the content and logistics of delivering of the BIG Project Workshop.

#### **4.1 HIV prevention delivered in group settings**

It is important at the outset to draw a distinction between 'group interventions', that is interventions delivered to groups of people as opposed to individuals – and 'groupwork interventions'. In contrast to 'group interventions', 'groupwork interventions' are based on specific theoretical principles, in particular assumptions about the therapeutic effect of dealing with problems or problem behaviours in a group, where the dynamics of the group are a feature of the intervention design and delivery and contribute directly to the therapeutic effects. 'Changing personal sexual practice' was a groupwork intervention, however the BIG Project Workshop was essentially a group intervention that incorporated elements of groupwork based approaches (Wanigaratne *et al.* 1996).

Groupwork and group interventions for HIV prevention became popular for four main reasons. The first was the presumed prevention benefit of targeting the highest risk groups of

people for the most intensive interventions. Epidemiological modelling has demonstrated that the greatest reduction in sexual transmission of HIV is likely to occur by changing the behaviour of those with the greatest risk of HIV exposure (Sepulveda *et al.* 1992). Gay men as a group, constitute one of these high-risk groups and surveillance data has demonstrated that a significant proportion of the sub-population at greatest risk could be accessed in GUM clinics (DoH 1994; Dodds *et al.* 1998; Dodds *et al.* 2000; Weatherburn *et al.* 1992; Weatherburn *et al.* 1997a).

The second reason for group interventions' popularity was their demonstrated effectiveness in other areas of health behaviour change. Experience treating other problem behaviours suggested that application of the same methods and approaches used – for example, in smoking cessation and the treatment of appetite disorders and drug addictions – could also work effectively in changing sexual behaviour for HIV prevention (Becker & Joseph 1988; Fishbein 2000; Fisher & Fisher 2000; Miller & Heather 1986; Prochaska *et al.* 1994a; Stevens & Hollis 1989). In other health areas interventions used professionally facilitated group sessions to allow patients to identify cognitive, emotional and situational variables that triggered behaviours. In group settings, patients could articulate their behaviour change goals, develop and rehearse strategies to deal with problem behaviours and acquired accurate knowledge and information about their condition (Prochaska *et al.* 1994b; Thornton & Catalan 1993). Interventions from addiction treatment in particular, suggested that developing skills to deal with lapses or slip-ups, and re-instigating positive behaviour following a lapse/slip-up, could also be usefully transferred to HIV prevention (Kelly 1994; Marlatt & Gordon 1985; Prochaska *et al.* 1994a; Wanigaratne *et al.* 1990).

The third attraction of group interventions related to the place small groups occupied in peoples' experience of other social interventions. Kalichman has argued that small group interventions are a natural extension of the practice of social development work with

stigmatised and marginalised populations (Kalichman & Hospers 1997). In these situations, social interventions often targeted entire communities but work through supporting numerous small groups of individuals (Kalichman 1998). In the same vein, King argued small group interventions are one of the original HIV prevention approaches and that they offer an appropriate and dynamic means of meeting evolving prevention needs over time, in the context of a changing HIV epidemic (King 1999).

The fourth attraction was straightforward economics. Psychotherapeutic intervention approaches usually require multiple sessions, physical infrastructure and highly trained facilitators, making them an expensive prevention option. Providing such resource intensive interventions in groups makes them more cost efficient (Billington & Wanigaratne 2000; Holtgrave & Pinkerton 2000).

#### **4.2 Evidence for effectiveness of group interventions with gay men**

In the 1990s, critical systematic reviews concluded that the best evidence for HIV prevention intervention effectiveness came from evaluations of small group and peer interventions (Holland *et al.* 1994; National Institutes of Health 1997; Oakley *et al.* 1996). The earliest experimental evaluations in HIV prevention with gay men involved controlled trials of either groupwork interventions or interventions delivered in group or social settings (Choi *et al.* 1996; Coates *et al.* 1989; Kelly *et al.* 1989; Peterson *et al.* 1996; Tudiver *et al.* 1992; Valdiserri *et al.* 1989). The results of these trials suggested that targeted group interventions held considerable promise. Oakley *et al.*, the National Institutes of Health and the CDC all agreed that small group approaches to HIV prevention were potentially effective, particularly if they included intensive skills-focused sessions, for example, condom-use and assertiveness training, that could improve an individual's safer sex negotiation skills. They also supported group interventions with a strong, explicit theoretical base (CDC 1999; National Institutes of

Health 1997; Oakley *et al.* 1996). They all recommended that these two types of interventions should be prioritised for further exploration, ideally in more RCTs (Oakley *et al.* 1996).

However, one question that remained unanswered was whether there was an optimal ‘dose’ of intervention required to stimulate individual behaviour change. Up to this point all the rigorously evaluated behavioural interventions had employed different approaches and different doses of intervention, varying from a single session over a few hours, to more than 80 hours over four months (Oakley *et al.* 1996). So while there was some evidence that group interventions worked, there was little indication how they should be delivered, and no indication of how much intervention was required to bring about sustained behaviour change. Given the cost and complexity of these interventions, a key challenge was to develop, deliver and demonstrate the effectiveness of a brief group intervention that would have broad potential for generalisability to a definable setting, such as GUM clinics.

#### **4.3 Theoretical basis of the ‘Changing personal sexual practice’ intervention**

Like many of the early theory-based prevention interventions, ‘Changing personal sexual practice’ incorporated elements from several health psychology and behaviour change models. Specifically, it was based on the main tenets of the Health Belief Model, and included constructs and approaches from the Transtheoretical Model of behaviour change and the Model of Behaviour Relapse (Becker 1974; Marlatt & Gordon 1985; Prochaska & DiClemente 1983; Rosenstock *et al.* 1994). This section summarises the respective contribution of each of these theories and models to the ‘Changing personal sexual practice’ intervention.

##### *The Health Belief Model*

The Health Belief Model provided the conceptual basis for the ‘Changing personal sexual practice’ intervention. Originally developed in the 1950s, it is essentially an explanatory



model. It posits that health behaviour is a function of an individual's socio-demographic characteristics, knowledge and attitudes (King 1999). Its underlying assumption is that individuals act to maximise the benefits of actions under their control and that in some instances perceived immediate gains lead to a disregard for potential long-term consequences (King 1999). This simple explanation fits neatly with the arguments of some of the different protagonists in the debate about 'relapse' in the early 1990s (Davies 1992; Hart 1992; Stall *et al.* 1990).

The Health Belief Model identifies a number of factors that influence health behaviour decisions that may be manipulated through interventions. The original list was developed in the 1960s and 1970s, and was later extended as understanding of the determinants of health decision-making increased (Becker 1974; Becker & Joseph 1988). The factors considered to be amenable to manipulation through interventions included: knowledge of health risk, personal perception of being at risk, perceived effectiveness of behaviour change, self-efficacy to enact behaviour change, belief in the power of technological cures or prevention, socio-demographic variables, social networks and perceived group and social norms (Becker & Joseph 1988; Rosenstock *et al.* 1994). According to the Health Belief Model, a person must hold certain beliefs in respect to a specific factor as a prerequisite to being able to initiate behaviour change (King 1999). For example, in the case of changing HIV sexual risk behaviours, an individual must first perceive HIV to be serious and themselves to be at risk, before they are able to respond to other factors such as belief in the effectiveness of the health recommendation (consistent condom-use) or the cues to action (knowing someone that is HIV positive) (Catania *et al.* 1990; King 1999; Rosenstock *et al.* 1994).

Reviews have concluded that the Health Belief Model's greatest contribution to HIV prevention development is as an explanatory framework to understand how sexual behaviour change occurs and, in turn, to identify the key variables whose manipulation will lead to

acceptance of, and compliance with, recommended health protective behaviour (Catania *et al.* 1990; Fisher & Fisher 2000; King 1999). But the same reviews also recognise the Health Belief Model offers little predictive guidance about how this process occurs or in what sequence variables should be manipulated (Catania *et al.* 1990; Fisher & Fisher 2000; Rosenstock *et al.* 1994). At this point most prevention researchers turn to other models or theories (Catania *et al.* 1990; Fisher & Fisher 2000; Rosenstock *et al.* 1994).

### *The Transtheoretical Model of behaviour change*

In the case of 'Changing personal sexual practice' this meant drawing on elements from other models to determine the actual intervention content. The main sources were models used in the understanding and treating of highly re-enforcing behavioural disorders, as it was believed these were better predictors of how the intervention should work in practice. The most important of these were Prochaska and DiClemente's Transtheoretical Model of behaviour change and Marlatt and Gordon's Model of the Relapse Process (Marlatt & Gordon 1985; Prochaska *et al.* 1994; Prochaska & DiClemente 1983; Prochaska & DiClemente 1986). The 'Changing personal sexual practice' team believed that these models explained the processes involved in adopting and maintaining safer sexual behaviour change, and offered a useful means of dealing with the likely problems of adopting safer sex and dealing with relapse from safer sex behaviour (Billington & Wanigaratne 2000; Wanigaratne *et al.* 1997).

Prochaska and DiClemente's original model of behaviour change was intended to explain the steps involved in smoking cessation (Prochaska & DiClemente 1983; Prochaska & DiClemente 1986; Prochaska *et al.* 1992). The model was intended to explain the processes involved in changing highly re-enforcing behaviours and, to identify the appropriate points where interventions were most likely to be effective in supporting behaviour change (Prochaska & DiClemente 1983; Prochaska *et al.* 1992). But the model's value in

understanding behaviour change relating to sexual behaviour came later (CDC AIDS Community Demonstration Projects 1999; Prochaska *et al.* 1994b). According to the Transtheoretical Model, change in relation to highly reinforcing behaviours occurs in a series of discrete stages, and the stages indicated appropriate points where different interventions were most likely to be effective (Prochaska & DiClemente 1983; Wanigaratne *et al.* 1997). Figure 3 describes the Transtheoretical Model's 'stages of behaviour change' in relation to initiation of condom-use for HIV prevention. The stages are labelled 'pre-contemplation', 'contemplation', 'preparation', 'action', 'maintenance', and 'relapse'. Although it appears that progression through the stages is linear, this is rarely the case. More often progress is more cyclical, that is an individual passes through each of the stages progressively until relapse occurs, which can happen at any point in the model. When this happens, the individual is likely to return to the pre-contemplation or contemplation stage from where the process begins again (Prochaska & DiClemente 1986). After experiencing a relapse, an individual will re-enter the cycle. The process is likely to be repeated several times until the

**Figure 3:** The stages involved in changing highly reinforcing behaviours using the example of initiating condom-use for HIV prevention

Stage	Associated cognitions
Pre-contemplation	Individual has not considered using condoms
Contemplation	Recognition of the need to use condoms
Preparation	Thinking about using condoms
Action	Will use condoms consistently for a period of less than 6 months
Maintenance	Used condoms consistently for more than 6 months
Relapse	Condom-use slip-up occasional and Then more often until complete relapse

individual eventually remains in the maintenance stage for a significant period. Having done this without any relapses, the individual may be considered to have successfully changed their behaviour, that is, they may be considered cured.

Prochaska and DiClemente suggest that after instigating behaviour change for the first time and reaching the first relapse, in each successive re-instigation, progression through the stages will be faster and the time to the maintenance stage shorter (Prochaska *et al.* 1992; Prochaska *et al.* 1994a). Because individuals accessing HIV prevention interventions to assist with behaviour change are likely to be in different stages relative to the Transtheoretical Model, separate interventions are needed to target each stage of the process. For example, according to Wanigaratne, based on the experience of treating addictions, interventions targeting the pre-contemplation stage may successfully use approaches like motivational interviewing, while relapse prevention interventions are most suited to those in the action and maintenance stages (Marlatt & Gordon 1985; Miller 1983; Miller & Rollnick 1991; Wanigaratne *et al.* 1990; Wanigaratne *et al.* 1997). The 'Changing personal sexual practice' intervention primarily targeted gay men in the pre-contemplation or contemplation stages and aimed to help participants expedite their progress through the subsequent stages, while at the same time equipping them with practical skills to avoid the setbacks and behaviour relapses (Billington & Wanigaratne 2000; Wanigaratne *et al.* 1997).

### *Model of the Relapse Process*

The third model contributing to the 'Changing personal sexual practice' intervention was Marlatt and Gordon's Model of the Relapse Process (Marlatt & Gordon 1985). Marlatt and Gordon's model, which draws directly on Prochaska and DiClemente's earlier work, is a cognitive-behavioural model specifically focused on maintaining behaviour change and avoiding relapse. This was considered to be a relevant factor in designing an intervention to support initiating and maintaining safer sex, especially as research confirmed that occasional

behaviour relapses were common, even among those who claimed to practise safer sex routinely (Marlatt & Gordon 1985; Wanigaratne *et al.* 1997). Marlatt and Gordon's model explained the cognitive processes involved in behaviour relapse and provides a basis for identifying and developing practical skills to avoid them, while at the same time developing personal empowerment skills (Marlatt & Gordon 1985; Wanigaratne *et al.* 1997). The model's comprehensive nature made it a useful framework for devising key component exercises in 'Changing personal sexual practice' intervention.

Elements of motivational interviewing, humanistic and group psychology, Buddhist philosophy and relaxation techniques were all to a lesser extent incorporated in specific exercises of the 'Changing personal sexual practice' intervention (Rogers 1961; Wanigaratne *et al.* 1997; Yalom 1975).

#### **4.4 Evolution of 'Changing personal sexual practice'**

The aims of the 'Changing personal sexual practice' intervention are described in Figure 4. 'Changing personal sexual practice' began as a series of seminars in 1990. The content of the first pilot seminars was formulated specifically in response to reports that many gay men seen in the clinic, were generally well informed about HIV and reducing transmission risk, but occasionally encountered difficulties either instigating safer sex or maintaining it in every situation (Billington & Wanigaratne 2000) (Personal Communication: Andrew Billington, Associate Director, Body Positive, April 1999). These observations confirmed what research findings from Australia and the United States had already described, in particular the cognitive and emotional aspects of failing to practise safer sex (Billington & Wanigaratne 2000; Fitzpatrick *et al.* 1990; Gold *et al.* 1991; Stall *et al.* 1989; Thornton & Catalan 1993).

The first 'Changing personal sexual practice' seminars included a small number of participants who were referred from the Mortimer Market Centre's men's GUM clinic

(Williams *et al.* 1993). The seminar lasted for 14 hours, divided into eight sessions. Nearly all participants came to the first seminar session but, from then on, between-session attrition was a problem and the overall completion rate was lower than anticipated. To respond to this, the team introduced a 'pre-group interview' to ensure selection of the most suitable candidates for the seminars and to reduce the between-session attrition. Those not considered suitable candidates for the intervention were offered other interventions, principally one-on-one work with a Health Advisor. In the seminar series following introduction of the pre-group interview between-session attrition fell by 15 to 20 % (Williams *et al.* 1993).

In response to the attrition problems and initial participant feedback, delivery of 'Changing personal sexual practice' was modified into a format of two evenings (2 hours/session) and two weekend days (5 hours/day). This proved to be more popular with participants and there

**Figure 4:** Key aims and objectives of the 'Changing personal sexual practice' groupwork-based intervention (Billington & Wanigaratne 2000; Wanigaratne *et al.* 1997)

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#### **Aims and Objectives**

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- To prevent the spread of HIV infection amongst gay men by helping participants to change their personal sexual practise to safer ones and enhance the probability of maintaining the changes.
  - To develop and support a greater understanding of HIV infection and its transmission.
  - To develop and support a greater sense of command and choice over sexual behaviour.
  - To develop and enhance sensual and sexual exploration and fun.
  - To increase self-esteem, self-confidence and overall satisfaction with daily life.
  - To explore strategies for negotiation and change.
- 

was a further reduction in between-session attrition (Billington *et al.* 1997; Billington & Wanigaratne 2000; Rodgers *et al.* 1997). There were also a number of small changes in the

facilitator team during the early years. However, apart from these, the intervention ran basically unaltered until 1996, when a series of re-branding changes were introduced. These involved giving the group a new name – ‘Getting the sex you want’ - and updating some of the supporting documentation so that it better reflected gay men’s changing experience of HIV and continued to be attractive and relevant to potential participants (Billington *et al.* 1997; Billington & Wanigaratne 2000; Rodgers *et al.* 1997).

‘Changing personal sexual practice’ was the subject to three small-scale evaluations. Process and pilot evaluations were undertaken in 1993 and 1995 and a third re-branding review followed the changes in 1996 (Billington *et al.* 1997; Rodgers *et al.* 1997; Wanigaratne *et al.* 1997; Williams *et al.* 1993). Williams *et al.*’s 1993 process evaluation concluded that the intervention was reaching and recruiting appropriate participants; that despite initial high between session attrition, overall completion rates were now relatively high (>70%); and that the group was being well received by those who attended (Williams *et al.* 1993). The 1995 pilot evaluation was described in more detail in the previous chapter (Wanigaratne *et al.* 1997). This evaluation focused on the intervention’s effects on specific outcomes, but was too small to draw meaningful conclusions (N = 26) (Wanigaratne *et al.* 1997). Nevertheless, the evaluators felt that ‘Changing personal sexual practice’ had achieved its aims of bringing about cognitive and situational self-confidence changes in keeping with HIV behavioural risk reduction (Wanigaratne *et al.* 1997). The third evaluation was entirely descriptive and focused on the intervention’s evolution in line with gay men’s changing experiences of HIV and the effects of the re-branding (Billington *et al.* 1997; Rodgers *et al.* 1997).

#### **4.5 Content of the ‘Changing personal sexual practice’ intervention**

This section summarises the content of each exercise of ‘Changing personal sexual practice’ (see Figure 5). More detailed descriptions have been published elsewhere (Billington & Wanigaratne 2000). Pairs of trained male and female facilitators, who were all qualified

counsellors or clinical psychologists, delivered the intervention, which took place in a non-clinical area of the Mortimer Market Centre.

### *Session 1 – Setting the frame*

The first session of ‘Changing personal sexual practice’ was in the evening and lasted two hours. The session’s objective was to set out the aims and intervention methods for participants. The facilitators briefly explained the principles of cognitive-behavioural therapy (CBT) and then with the participants, set ground rules that included agreements on confidentiality, respect for others’ views and timekeeping (Beck *et al.* 1979; Billington & Wanigaratne 2000).

The only exercise in the first evening session looked at setting personal goals. In the exercise, the facilitators demonstrated a process by which personal goals can be broken down into a series of smaller incremental steps. This introduced participants to the concept of developing self-motivation by measuring one’s own achievements in the process of attaining a larger goal. The facilitators also demonstrated how these principles could also be applied to a ‘personal sexual goal’, and then encouraged participants to try for themselves. Each of the four group meetings ended with a guided relaxation exercise that was led by one of the facilitators.

### *Session 2*

The next two meetings were whole-day sessions lasting five hours (not including breaks and lunch). These were held on a weekend day, one week apart. Each meeting was divided into



**Figure 5: Description of the exercises, delivery and learning objectives of the ‘Changing personal sexual practice’ groupwork intervention**

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**Session 1 – Wednesday evening (2 hours) – Setting the frame**

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<u>Exercise and delivery approach</u>	<u>Objectives/Skills Acquired</u>
Introductions – Facilitators & group members (working in pairs)	Appreciate what can be learned from talking, questioning, listening & whole group feedback processes
Outlining workshop approach & CBT (facilitators only)	Introduce CBT, aims & objectives of group
Developing ground-rules (working as whole group)	Respect for others’ views and importance of confidentiality and safe space to disclose
<i>‘Setting personal sexual goals’</i> (working in pairs)	Break down goals to smaller units that are realistic, achievable & measurable
<i>‘Decision Balance Sheet’</i> – Introduction and complete as ‘homework’ (facilitators)	Understand behaviour change entails gains and losses. Assess own readiness and motivation

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**Session 2 – Saturday (5 hours)**

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Review <i>‘Decision Balance Sheet’</i> (working individually, in pairs & whole group feedback)	Understand degree of change involved in achieving a single goal. Assess motivation – Is change worth it? Effort involved? Gains & Losses
Recognising and coping with stress and anxiety (working in pairs, then whole group discussion)	Define stress & anxiety. Recognise physical, emotional & behavioural symptoms, specifically regarding sex. Identify individual coping patterns. Learn about alternative coping methods
<i>‘What really turns me on?’</i> (working in pairs, then small groups)	Eroticising safer sex. Develop capacity to talk openly about sex and arousal. Learn that what is sexually exciting is often low risk for HIV
<i>‘High risk situations’ &amp; ‘Hotspots’</i> (working in small groups respond to statement – <i>‘I am most likely to have unsafe sex when ...’</i> )	Learn unsafe sex may be triggered response to certain circumstances, e.g. place, mood, social pressures, thoughts/attitudes & relationships
<i>‘Hotspots situation report’</i> (complete individually as homework).	Reflect on problematic sexual episodes. Identify ‘triggers’ & behaviour responses
<i>‘Body image exercise’</i> (working in pairs, whole group feedback)	Understand relationship between body image, positive feedback, self-perceptions, self-esteem and self-confidence. Recognise links between body image, self-esteem and sexual assertiveness
Guided relaxation (facilitator led)	Learn relaxation and meditation techniques, and the value of ‘switching-off’

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**Figure 5:** (cont'd) Description of the exercises, delivery and learning objectives of the 'Changing personal sexual practice' groupwork intervention

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**Session 3 – Sunday (one week later) (5 hours)**

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<i>'High-risk situations 2'</i> – Review of <i>'Hotspots situation report'</i> (Working in pairs, whole group feedback)	Learn that individuals have different but often similar experience of 'triggers'. Learn that it is possible to anticipate 'triggers' and to develop coping strategies to deal with them
<i>'Safer sex experts – Questions &amp; Answers'</i> (facilitator led, participant delivered)	Answering one another's questions; learn small-group problem-solving skills. Understand that perceived lack of factual knowledge has not been an obstacle to initiating change. Learn and practice correct condom-use skills. Facilitator input as necessary
<i>'Cognitive aspects of unsafe sex'</i> (facilitator presentation)	Introduce different patterns of thinking that happen before and during episodes of unsafe sex (e.g. 'denial', 'seemingly irrelevant decisions' & 'rule violation effect')
Negotiation of safer sex (working in small groups).	Identify, describe and model successful sexual negotiation skills. Share techniques for effective communication with current and future sexual partners
<i>'Lifestyle Balance Sheet'</i> (working individually and group discussion)	Understand achieving balance and incorporating change into lifestyle is essential to maintaining change
Guided relaxation (facilitator led)	Learn more relaxation and meditation techniques, re-enforce value of 'switching-off'

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**Session 4 – Wednesday evening (2 hours) – Consolidating changes**

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Implementing change – debriefing experience so far (whole group discussion)	Re-enforce understanding that change is incremental, reflect on realistic, achievable and measurable steps to change
Evaluation – verbal and written (working as individuals, whole group feedback)	Reflection and stock-taking is part of change process – <i>How far have I come?</i>
Future work (facilitator led).	Learn about options to continue the work started in workshop
Guided relaxation (facilitator led)	Re-enforce relaxation techniques and value of 'switching-off'

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five exercises. The first exercise in this session used Janis and Mann's '*Decision Balance Sheet*' to assess participants' readiness for change and to increase personal motivation for behaviour change (see Appendix 3) (Janis & Mann 1977). Participants completed the '*Decision Balance Sheet*', using the same personal sexual goal that they had described in the previous evening session to illustrate that in addition to the positive aspects of achieving a goal, there are also losses. Although the positive gains are most often seen to outweigh the losses, failing to recognise the losses and to deal with them appropriately may allow them to sabotage or hi-jack the change process and sap one's personal motivation (Janis & Mann 1977).

Meichenbaum's concept of stress inoculation provided the basis for the second exercise of the day (Meichenbaum 1977). This concept proposes that an individual needs to recognise and appreciate the physical and cognitive symptoms and responses they experience in stress- and anxiety-producing situations as a first step to developing appropriate personal coping strategies (Meichenbaum 1977). In '*Changing personal sexual practice*', the concept was expanded further by introducing the central cognitive-behavioural principle of linking thoughts, feelings and actions and using the example of experiences of stress and anxiety as an illustration (Barlow 1988). Working in pairs, the participants first defined stress and anxiety for themselves. Then they named the emotional, physical and behavioural symptoms they experienced when either stressed or anxious. Next they looked at their own personal coping strategies and at ways of making them more effective by breaking the 'thoughts, feelings, actions' linkage (Barlow 1988). In a second example they then applied these same approaches to a situation where sex was the source of stress or part of the means of coping with a stressful situation (Billington & Wanigaratne 2000).

'*What really turns me on?*' was an exercise intended to encourage explicit and open discussion of sex, as part of desensitising and demystifying the subject for the group. A

secondary aim was to demonstrate that many of the sexual activities participants fantasised about were in fact unlikely to carry significant HIV transmission risk. The exercise involved first working in small groups to compile a list of what participants found sexually arousing. Then, reconvening as a whole group, the facilitators used the opportunity to examine the lists with the participants to highlight the points about reduced HIV transmission risk associated with many of their fantasies.

The day's fourth exercise used Roffman's concept of 'Hotspots' to introduce participants to the idea that having unsafe sex may be an unintended or undesired outcome of certain 'trigger' situations. Roffman's concept proposes that difficulties practicing safer sex are often linked to certain situations or specific types of partners (Roffman *et al.* 1992). The idea of 'trigger' situations is central to Marlatt and Gordon's Model of the Relapse Process and therefore, the two fit well together. In this exercise participants identified a situation where they were likely to end up having unsafe sex and then described how the scenario played out. The aim was to demonstrate two key features of trigger situations: first, that it is possible to anticipate the Hotspot situations that accompany them; and second, that having this knowledge made it easier to develop appropriate strategies to either avoid Hotspots or, at least, employ coping strategies that support rather than undermine personal self-efficacy. As part of this exercise, participants were given a '*Hotspots situation report*' to complete at home. The '*Hotspots situation report*' was simply a sheet of paper that provided a formulaic approach with which to analyse different types of Hotspot situations and to begin planning alternative coping strategies (see Appendix 3) (Roffman *et al.* 1992). The '*Hotspots situation report*' also introduced the idea of having pre-planned and rehearsed coping strategies for use in trigger situations (Billington & Wanigaratne 2000).

The '*Body image exercise*' was conceived as a response to research findings that showed both self-esteem and negative body image were associated with poor sexual assertiveness and

difficulties adopting safer sex (Horn & Chetwynd 1989). As Roffman also argued, low self-esteem that was linked to poor body image could be a trigger in certain '*Hotspot situations*' (Billington & Wanigaratne 2000; Roffman *et al* 1992). The aim of '*Body image exercise*' was to challenge participants' individual perceptions of their bodies, and thereby enhance their self-esteem. Working in pairs, the participants lay on the floor and traced an outline of each other's body on a very large sheet of paper. In turn, they then highlighted what they liked and disliked about their own bodies, and what they would like to change using the outline on the floor. They discussed these with each other using positive feedback approaches and challenging negative or unfounded views. The final stage of the exercise involved a group discussion in which the facilitators explained the relationship between poor body image and difficulties with safer sex, and how negative perceptions affected personal assertiveness in sexual situations.

### *Session 3*

The third session also lasted for a full day (5 hours) and followed one week later. At the end of the second session, in addition to completing the '*Hotspots situation report*', participants were encouraged to try out some of the new skills they had acquired. The third session began with a review of the '*Hotspots situation report*' and an informal feedback about participants' experience of using their new skills. This led into the second exercise in which the facilitators discussed different anticipatory and coping strategies the participants had developed, based on the '*Hotspots situation report*'. The purpose was to demonstrate how important it is for coping strategies be genuinely realistic for the situations where they are going to be used. The facilitators noted that, if coping strategies were not realistic, participants ran the risk of failing, and this in turn would undermine their self-efficacy.

The Safer Sex Experts exercise was a question and answer session in which participants drew up a list of questions regarding any aspect of sex and safer sex and then, working in groups,

answered them, only calling on the facilitators when there was disagreement or uncertainty about the correct answer. In this exercise each participant had the opportunity to role-play, performing a condom demonstration in one of a number of different fictitious scenarios. The aims of the exercise were to encourage joint problem solving, to highlight and re-enforce participants' already extensive safer sex and HIV knowledge and to enhance their condom-use skills and condom self-efficacy.

The day's third exercise was a facilitator-led discussion of the cognitive aspects of unsafe sex. In this, the facilitators introduced three different patterns of thinking that could all be linked to a person's failure to practise safer sex. These were: 1) *Denial* – failing to accept that underlying thoughts actually influence decisions to have unsafe sex; 2) *Seemingly irrelevant decisions* – thoughts not recognised as part of the decision to have unsafe sex, and 3) *Rule violation effect* – whereby failure to adhere to safer sex is interpreted as evidence that the goal itself is unattainable (Billington & Wanigaratne 2000). In a group discussion participants related their own experience of each of these thought patterns and how, being aware of them and equipped with new coping skills, they could actually challenge them.

In the next exercise participants were given the opportunity to apply this knowledge by devising scenarios and scripts for a video specifically dealing with negotiating enjoyable and safer sex (Billington & Wanigaratne 2000). In the exercise the participants had the opportunity to rehearse different negotiation techniques for use with current and future sexual partners through role-plays and as part of devising the video script.

The penultimate exercise of the session focused on lifestyle balance. According to Marlatt and Gordon's model, lifestyle balance is central to maintaining behaviour change in the long term (Marlatt & Gordon 1985). The lifestyle balance concept concerns the way everyday stressors and pleasurable activities are balanced in day-to-day life. In the exercise

participants completed a grid of nine squares according to what activities filled their days, and then attached values (0–100%) indicating the percentage of time taken up by each, such that the total of the nine squares equalled 100%. They were then asked to reconsider the values and to re-assign them so that they reflected what the participant would actually like the balance to be (Billington & Wanigaratne 2000). The purpose was to demonstrate that changing the balance of one's life actually involves more than changing just one aspect of it.

#### *Session 4 – Consolidating changes*

The final two-hour evening session focused on consolidating skills acquired during the previous sessions. It had no specific exercises, except the guided relaxation at the end. The purpose of the final session was to provide an opportunity for participants to debrief their experiences of the intervention and of implementing their new skills. It also offered a chance for individual discussion with the facilitators about different options for future behaviour change work and how to obtain appropriate HIV prevention support if they felt they needed it in the future.

#### **4.6 Lessons learnt from 'Changing personal sexual practice'**

Over the years, important lessons were learned from 'Changing personal sexual practice' that had direct relevance to the design and content of the BIG Project Workshop. Much of this came from participant and facilitator feedback and the evaluations in 1993 and 1995 (Wanigaratne *et al.* 1997; Williams *et al.* 1993).

#### *Referral and eligibility*

When 'Changing personal sexual practice' started, many of the men attending were adopting safer sex behaviours for the first time. Over time the most common presentation changed such that the main issues for presenting men were likely to be difficulties maintaining safer sex in the long term and developing personal strategies to reduce HIV risk generally

(Billington *et al.* 1997; Billington *et al.* 1995; Kippax *et al.* 1993; Rogers *et al.* 1997). The 'Changing personal sexual practice' team attempted to respond to this by broadening the referral and eligibility criteria of the group (Billington & Wanigaratne 2000). New eligibility criteria also made it possible to accept referrals from outside of the Mortimer Market Centre clinics (Billington & Wanigaratne 2000). However, with these new referral and eligibility criteria, the pre-group interview described earlier became an even more important part of the participant selection and group preparation process. To be able to adequately accommodate the potentially wide range of presenting issues, it was necessary to make sure the men coming to the group were sufficiently motivated to address sexual behaviour and behaviour change, and that they were suitable for a groupwork intervention. At an administrative level it was also important to ensure there was a complementary mix of presenting issues among the participants in each group. For the facilitators, information from the pre-group interview was important to help them know who to expect and to anticipate issues that were likely to arise (Billington & Wanigaratne 2000).

#### *Identification of core exercises*

Evaluations and feedback identified a core set of intervention exercises that were consistently highly rated by participants (Billington & Wanigaratne 2000; Wanigaratne *et al.* 1997). These included: setting personal goals, the decision balance sheet, the '*Hotspots situation report*', cognitive aspects of safer sex, the lifestyle balance sheet, safer sex experts and the '*Body image exercise*' (Billington & Wanigaratne 2000). Identification of this core set of exercises made it possible to modify the time spent on individual exercises, according to the particular needs of the group without losing the essential cognitive-behavioural components (Billington & Wanigaratne 2000). This was important in designing the BIG Project Workshop which, to be generalisable, would need to fit in with what was feasible in a busy clinic.



### *Usefulness of eclectic theoretical approaches*

Not all of the core exercises were linked to the underlying cognitive-behavioural approach of 'Changing personal sexual practice'. For example, the safer sex experts, '*Hotspots situation report*' and '*Body image exercise*'s drew on other theoretical models. However, it was this eclectic mix of models and exercises identified by participants that was seen as one of the intervention's strengths (Billington & Wanigaratne 2000; Wanigaratne *et al.* 1997; Williams *et al.* 1993). The 'Changing personal sexual practice' team argued that inclusion of different models was central to their success, claiming that it helped to explain why participants found the overall cognitive-behavioural techniques acceptable and helpful (Billington & Wanigaratne 2000).

### *Facilitators, confidentiality and group safety*

The early groups were delivered by male and female facilitators. However, participant evaluations consistently stated a preference for gay men in this role (Billington & Wanigaratne 2000). Although the intervention was structured and facilitators were provided with guidance on exercise aims, facilitators still required experience of managing group interventions to ensure all the exercises were adequately covered within the available time. They also needed to recognise the needs of different group members and to be able deal with complex issues that might arise, while at the same time retaining the group's cognitive-behavioural focus (Billington & Wanigaratne 2000). It was a demanding task and therefore important that facilitators were supported with high quality clinical supervision after each group (Billington & Wanigaratne 2000).

Providing a safe, confidential environment where men could openly discuss their anxieties about safer sex without fear of being judged was also rated as among the most useful aspects of 'Changing personal sexual practice' (Billington & Wanigaratne 2000). Creating this safe space was achieved by establishing ground rules at the earliest possible point, ensuring

participants interacted with each other in different ways during each of the sessions, particularly during exercises that involved disclosure of any sensitive or highly personal information. The guided relaxation at the end of each session was also important to defuse participants' sensitive disclosures.

#### **4.7 Designing the BIG Project Workshop intervention**

In designing the BIG Project Workshop there were three main aims:

- 1) To ensure the intervention adhered to theoretical principles and incorporated as many of the same exercises from 'Changing personal sexual practice' as possible.
- 2) To devise an intervention that could be delivered in fewer sessions and less time than 'Changing personal sexual practice'.
- 3) To create an intervention that was acceptable and feasible within a busy routine GUM clinic setting.

An intervention that met these criteria, and that was shown to be effective in a rigorous evaluation, would provide an important addition to GUM clinics' current repertoire of sexual health promotion and HIV prevention activities. Figure 6 illustrates the final format of the BIG Project Workshop as tested in the main trial. It can be compared with the earlier 'Changing personal sexual practice' description (see Figure 5) to see the similarities and differences between the two intervention packages.

##### *Reduced overall running time*

The original plan was that the intervention should run no more than three sessions; a total of 12 hours (two 3-hour evening sessions and one 6 hour weekend day). However, as described in more detail in the next chapter, during two pilot runs of the workshop, there was unacceptably high between-session attrition and so, for the main trial, a one-day 7-hour single session format was used.

### *Exercise timing, format and delivery*

In this single session format, time allocated for individual exercises was strictly limited. To ensure consistent delivery of all the exercises, workshop facilitators were provided with special training and comprehensive facilitators' notes for use during the workshop (see Appendix 4). The introduction of a BIG Project Participant's Workbook added more structure and gave participants an opportunity to preview the workshop exercises in advance of the day (see Appendix 3). To limit the possibility of exercises running over time, each exercise was delivered by one facilitator, and the other served as an unofficial timekeeper and made sure everything was ready for the next.

### *Component exercises*

All the core exercises described earlier were included in the BIG Project Workshop, and delivered in the same way as in 'Changing personal sexual practice' with the exception of the '*High risk situations/ Hotspots situation report*' exercise. In 'Changing personal sexual practice' this exercise was undertaken in four steps that overlapped the two all-day sessions. The initial discussion happened at the end of the first day, and '*Hotspots situation report*' report was completed as homework. The group discussion of the '*Hotspots situation report*' and developing anticipatory and coping strategies took place at the beginning of the second all-day session. In the BIG Project Workshop, the group discussion was replaced with a facilitator-led presentation of 'positive self-talk' as a coping strategy. 'Positive self-talk' refers to people's constant internal dialogue that is usually more apparent in and around stressful situations. The facilitators demonstrated how 'positive self-talk' could be used as a tool to help deal with stressful situations, specifically when implementing a previously rehearsed coping strategy. Even though this was a significant deviation from the original intervention, it was still in keeping with the overall cognitive-behavioural approach (Marlatt & Gordon 1985).

**Figure 6:** Description of individual component sessions of the BIG Project Workshop including the learning objectives and skills acquired, materials and methods used

<b>Exercise</b>	<b>Learning Objectives/Skills Acquired</b>	<b>Materials &amp; Delivery</b>
Workshop content	Explanation & familiarisation with intervention exercises	BIG Project Participant Workbook (provided in advance) (see Appendix 3)
Introduction	Welcome, principles of CBT, importance of ground-rules	Prepared flipcharts (group discussion)
Setting personal sexual goals	Setting realistic, measurable & achievable goals. Recognising sexual goals	Workbook, prepared flipcharts, practical exercise (in pairs, group discussion)
'Decision balance sheet'	Appreciate the gains and losses associated with achieving goals. Assessing personal motivation	Workbook, practical exercise (individually & small groups)
Understanding anxiety & stress, and appropriate coping strategies	Recognise physiological symptoms and cognitive processes associated with anxiety and stress. Acquire new coping skills and relaxation techniques	Flipcharts. Describe personal experience of physical and emotional sensations of stressful situations (in pairs, whole group discussion)
High risk situations	Awareness of and coping in high-risk situations. Develop 'positive self-talk' skills	Prepared flipcharts, description in workbook (individually, whole group feedback & discussion)
Body image & self-esteem	Appreciate relationship between self-esteem and body image; challenge negative self-perceptions	Large sheets of paper & markers (in pairs, whole group discussion)
STI, safer sex, condoms	Information, education & condom-use skills	Flipcharts, condoms, bananas & role-play (in small groups)
Lifestyle balance	Place goals within lifestyle context. Develop prioritisation skills	Workbook (individually, whole group discussion)
Moving forward	Information giving	Workbook (group discussion)

### *The BIG Project Participant's Workbook*

The decision to include a participant workbook was taken early on in developing the BIG Project Workshop intervention (see Appendix 3). The workbook would serve three purposes. First, it would familiarise participants with the intervention. Second, using a workbook would give additional structure to the intervention. And third, the workbook would give participants a useful resource they could take home and work through again in their own time. From a theoretical perspective, this was the main purpose and fit well with growing belief that to be effective in the longer term it was important in behavioural interventions to provide participants with intervention booster sessions (Coates *et al.* 1996a). Providing participants with a workbook that covered the entire intervention, and that they could work through on their own meant that they effectively had everything necessary to receive a booster session 'on demand' (Personal communication: Shamil Wanigaratne, Consultant Clinical Psychologist, South London and The Maudsley NHS Trust, April 1999).

### *Pre-group interview*

Although the pre-group interview was considered to be important in the success of 'Changing personal sexual practice', it was not practical to retain this in the main trial. It was intended that the evaluation be undertaken in circumstances that as closely as possible approximated the 'real life' conditions of a busy GUM clinic. In 'real life' it would not be feasible to undertake a detailed assessment of each client's personal motivation for behaviour change, personal issues around safer sex and suitability for groupwork (Kalichman *et al.* 1999; St Leger *et al.* 1992; Stephenson & Imrie 1998). More importantly, given the pragmatic nature of the evaluation, this sort of detailed individual assessment and subsequent exclusion of some men would have reduced the generalisability of the results and subverted the benefit obtained through participant randomisation (Kalichman *et al.* 1999; Schultz 1995; Stephenson & Imrie 1998).

### *Facilitators*

Having qualified, well-supported facilitators was deemed to be one of the cornerstones of the success of 'Changing personal sexual practice' (Billington & Wanigaratne 2000). Although participant feedback indicated a preference for gay men facilitators, there was no specific evidence that women facilitators were any less effective (Billington & Wanigaratne 2000; Williams *et al.* 1993). Facilitators for the BIG Project Workshop were recruited from the Mortimer Market Centre's Health Advisor team and other clinical staff trained in counselling. All facilitators were provided with 10 hours (2 days) of intensive training in delivering the BIG Project Workshops. This was followed up with a half-day refresher seminar after 3 months. Each facilitator was assigned a partner (co-facilitator) according to their counselling experience and training in groupwork facilitation.

### *Summary*

The design of the BIG Project Workshop drew heavily on the experiences of the original 'Changing personal sexual practice' team, as well as two small-scale evaluations and participant feedback. The core exercises identified by the original implementation team were retained in the BIG Project Workshop and other changes were kept to a minimum. There were some changes in the logistics, but these were intended to ensure the BIG Project Workshop would be acceptable to clinic attenders and feasible to deliver within existing clinic staffing levels. These logistical changes were: 1) reducing the overall running time to a single 7-hour session; 2) providing the intervention in a more structured format; 3) introducing a participant workbook; 4) eliminating the pre-group interview, and 5) extending the pool of potential facilitators by drawing on the clinic's Health Advisors and other staff with counselling training.

#### 4.8 Conclusions

The BIG Project Workshop intervention fulfilled the key requirements of a candidate intervention for an RCT evaluation. Firstly, it incorporated much of the current expert thinking about the value, format and delivery approaches of behavioural interventions delivered in groups (Coates *et al.* 1996a; Coates *et al.* 1996b; Oakley *et al.* 1996). Secondly, it was explicitly theory-based and incorporated this in its design and selection of some of the component exercises (Coates *et al.* 1996b; Kelly *et al.* 1989; Oakley *et al.* 1996). It was explicitly based on accepted models of behaviour change, and the rationale, aims and objectives of each exercise had already been tested in preliminary work. Thirdly, over the years, 'Changing personal sexual practice' had shown itself to be adaptable to gay men's changing circumstances and experience of the HIV/AIDS epidemic and durable in its ability to attract participants (Billington & Wanigaratne 2000). Finally, through identification of a set of core exercises, it was possible to design a shorter intervention that, with the benefit of additional structure, could be delivered in a busy clinical setting. If the trial results demonstrated the BIG Project Workshop was effective, these two final points would help ensure its acceptability and likely adoption in other GUM clinic settings.

## **Chapter 5**

### **Design of the randomised controlled trial evaluation**

#### **5.0 Introduction**

This chapter describes the design of the RCT evaluation and covers all of the key methodological points highlighted in the revised CONSORT (Consolidated Standards of Reporting Trials) guidance for improved reporting of simple two-group parallel RCTs (Moher *et al.* 2001). The chapter also explains steps involved in implementing key aspects of the trial and the methodology used in the process and quality assurance evaluations. The originally funded research proposal is included as Appendix 5.

#### **5.1 Trial hypothesis and objectives**

The main hypothesis to be tested in the trial was that providing brief, intense cognitive-behavioural intervention workshops to groups of ‘high-risk’ gay and bisexual men attending GUM clinic services would improve their overall sexual health by:

- Reducing new STI diagnoses and self-reported high-risk sexual behaviours;



- Improving adherence to safer sex and risk reduction advice;
- Fostering better use of HIV prevention services and enhancing general health and wellbeing.

To test each of these hypotheses satisfactorily, the RCT design had to meet five essential requirements:

1. The trial had to be adequately powered to compare the frequency of new STI diagnoses and specific high-risk sexual behaviours between men randomised to receive the standard management and attend the BIG Project Workshop (Intervention group) and those who received the standard management alone (Control group);
2. It needed to have appropriate data collection procedures and instruments to measure accurately pre-specified biological and behavioural endpoints;
3. The trial design needed to be able to provide high quality process data to assess the overall quality and fidelity of the intervention's delivery and to generate explanations for the trial results;
4. The trial design needed to include measures of the intervention's acceptability and feasibility both within the target group and among the clinic staff;
5. The trial design needed to be sufficiently robust to demonstrate external validity (generalisability) of the results to other GUM clinical settings (Moher *et al.* 2001; Pocock 1983; St Leger *et al.* 1992; Stephenson & Imrie 1998).

## **5.2 Setting and study population**

As stated earlier, the trial setting was a large central London GUM clinic, the Mortimer Market Centre. At the time of the evaluation, the Mortimer Market Centre was the largest GUM clinic in Europe, recording approximately 85,000 attendances annually. Trial participants were recruited from three source clinics: 1) Mortimer Market Centre's routine

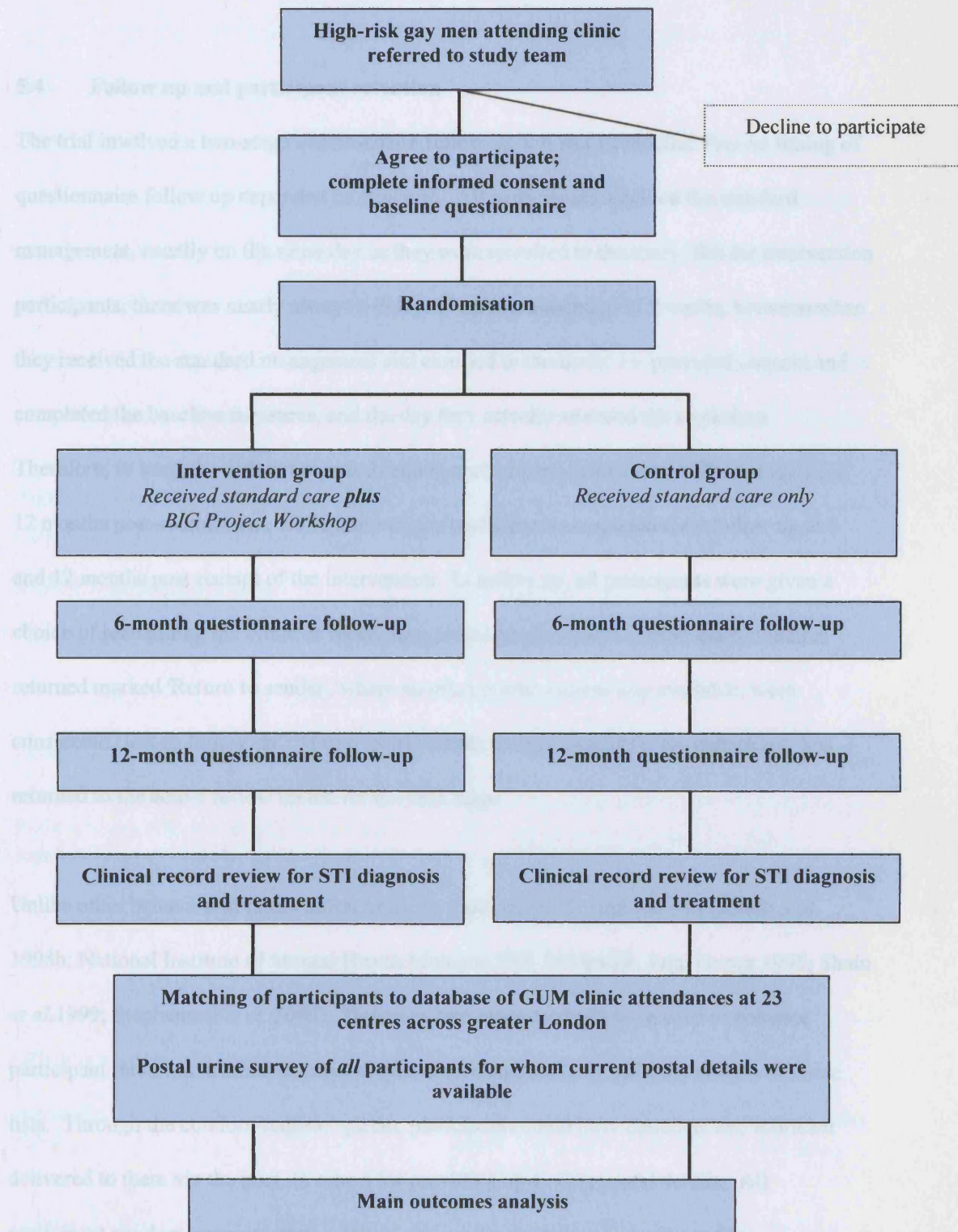
men's GUM service; 2) the Axis Clinic – a weekly dedicated young gay men's service, and 3) the Archway Sexual Health Clinic in North London.

The study population was gay and bisexual men at 'high-risk' of STI and HIV infection attending these GUM services. Community surveys have shown that gay and bisexual men who attend GUM services have consistently higher-risk sexual lifestyles with respect to both HIV and STI than other gay men (Dodds *et al.* 1998; Dodds *et al.* 2000; Hickson *et al.* 1996; Imrie *et al.* 1999; Nardone *et al.* 1998). At the Mortimer Market Centre, gay and bisexual men account for about one-third of registered patients and more than 50% of all attendances. At the time of the trial, the Axis Clinic had nearly 700 attendances annually, all self-identified gay or bisexual men less than 26 years of age. Surveys in the clinic and clinical audit at the time showed that Axis attenders reported more high-risk sexual behaviour, and had significantly higher gonorrhoea rates, than similarly aged gay men attending the routine GUM service (Bean *et al.* 1999; Billington *et al.* 1997a; Imrie *et al.* 1999). The Archway Sexual Health Clinic had approximately 16,000 attendances annually, but substantially fewer gay and bisexual men. The Archway Sexual Health Clinic provides no special or dedicated services for gay and bisexual men.

### **5.3 Trial design**

The trial design was a pragmatic two-group parallel comparison between the standard management, plus the intervention, and the standard management alone, within a busy clinical setting. Figure 7 depicts the overall trial design. Participants were allocated in equal numbers to each arm. The primary trial endpoint was new STI diagnoses during the 12 month follow up, based on a record review of the Mortimer Market Centre clinic databases. The main secondary outcome was reduced high-risk sexual behaviour based on a range of behavioural indicators obtained from self-completed questionnaires collected at baseline and

**Figure 7:** Design of the randomised controlled trial



two follow ups at 6 and 12 months. Analysis of the trial endpoints was undertaken only after the questionnaire follow up, clinic record review and postal urine survey were complete.

#### **5.4 Follow up and participant retention**

The trial involved a two-stage questionnaire follow up at 6 and 12 months. Precise timing of questionnaire follow up depended on trial arm. All participants received the standard management, usually on the same day as they were recruited to the study. But for intervention participants, there was nearly always a delay, of up to a maximum of 9 weeks, between when they received the standard management and enrolled in the study, i.e. provided consent and completed the baseline measures, and the day they actually attended the workshop.

Therefore, to keep the follow up periods equal, control participants were followed up 6 and 12 months post-recruitment, while intervention participants completed their follow up at 6 and 12 months post receipt of the intervention. In follow up, all participants were given a choice of reattending the clinic or receiving a postal questionnaire. Postal questionnaires returned marked 'Return to sender', where no other postal address was available, were considered 'lost to follow up'. If new postal details became available, the participant was returned to the active follow up list for the next stage.

Unlike other behavioural intervention trials, no cash payments were offered (Kamb *et al.* 1998b; National Institute of Mental Health Multisite HIV Prevention Trial Group 1998; Shain *et al.* 1999; Stephenson *et al.* 2000). However, two other methods were used to enhance participant retention: a condom-request system (see Appendix 6) and daily review of clinic lists. Through the condom-request system, participants could have condoms and lubricant delivered to them via the post, in return for providing up-to-date postal details. All participant condom-requests were retained and used to update postal address files. Appointment lists for the clinic were compared with the list of trial participants daily. Trial participants attending the clinic, for whom postal contact details were incorrect or missing,

were asked by clinic reception to provide up-to-date information for their clinical records and these were in turn passed on to the trial team.

## 5.5 Trial outcomes

All trial outcomes were compared between the trial arms (see Figure 8). The primary trial endpoint was the likelihood of having a new STI diagnosed during the 12 month follow up based on clinic records. The main secondary endpoint was reduction in self-reported high-risk sexual behaviours. Behavioural indicators used to assess this outcome included total numbers of sexual contacts, numbers of AI partners, UAI, regular male partnerships, being in a monogamous partnership, last UAI episode with a partner of same HIV status, HIV testing

**Figure 8:** Trial outcome measures and pre-selected outcome indicators

<b><u>Primary outcome measure</u></b>	<b><u>Indicators</u></b>
STI acquired during the follow up period	<ul style="list-style-type: none"> <li>• KC-60<sup>(1)</sup> and laboratory diagnoses from clinic computer records</li> </ul>
<b><u>Main secondary outcome measure</u></b>	
Reduced high-risk sexual behaviours and improved knowledge and health status	<ul style="list-style-type: none"> <li>• Number of sexual contacts in last month and last year</li> <li>• Total AI partners in last month and last year</li> <li>• Any UAI in last month and last year</li> <li>• Regular male partner</li> <li>• Monogamous relationships</li> <li>• Last UAI with partner of same HIV status</li> <li>• HIV test in last year</li> <li>• Recreational drug use in last year</li> </ul>
<b>Other secondary outcomes</b>	
Intermediate indicators of an intervention effect	<ul style="list-style-type: none"> <li>• Scores compared from attitudinal and psychometric scales across baseline and follow up questionnaires</li> </ul>
Uptake of other HIV prevention services	<ul style="list-style-type: none"> <li>• Prevention activities attended and services used</li> </ul>

(1) The KC-60 diagnosis code is the main routine measure of activity and diagnoses GUM clinics provided to the Department of Health for routine surveillance and production of health statistics (PHLS AIDS & STD Centre, 2002).

in last year, recreational drug use and self-reported treatment of an STI. Other secondary outcomes of interest included intermediate indicators of any intervention effect based on scores on attitudinal and psychometric scales and uptake of other prevention services.

## **5.6 Eligibility and exclusions**

### *Eligibility*

To maximise the trial's external validity, eligibility was kept simple and inclusive. All self-identified gay and bisexual men judged by clinic staff, that is doctors, nurses and Health Advisors, to be 'high-risk' were eligible to participate. In 'real-life' this would be an expensive intervention for GUM clinics to provide, therefore it was considered most appropriate to test the intervention in a population where, if effective, it would be likely to have the greatest clinical impact. Eligibility guidance, based on research evidence, was developed to assist clinic staff to identify men who would be most suitable for referral to the trial. These were simplified to three characterisations based on biological, behavioural and psycho-social determinants of high-risk. Gay and bisexual men were defined as being 'high-risk', and therefore eligible for referral to the trial, if they fulfilled one or more of the following criteria:

- **Biological** – Men presenting with a first clinical episode of an STI, presumed to have been homosexually acquired through unprotected oral or anal intercourse. This included first clinical episodes of viral infections (Hepatitis B, genital and peri-anal herpes and warts) and new bacterial infections (primary and secondary syphilis, gonorrhoea, chlamydia, and non-specific urethritis (NSU)).
- **Behavioural** – Men reporting UAI in the previous 12 months, with one or more regular or casual partners of unknown or discordant HIV serostatus.
- **Psycho-social** – Any self-identified gay or bisexual man expressing concerns about the safety of, or HIV risk associated with, his sexual practice. Men referred to the trial based

on this criterion alone, were for the most part either sexually inexperienced or sexually experienced, but in need of support to consolidate their safer sex skills.

The majority of men referred to the study met more than one of the eligibility criteria.

### *Exclusions*

The only men explicitly excluded were:

- Men attending the clinic in other than routine circumstances, for example to receive a positive HIV test result or following a sexual assault;
- Men who knew at the time of referral that they would be unable to attend the intervention or complete the full follow up.

Knowledge of HIV status was not an eligibility requirement and men with diagnosed HIV infection were allowed to participate with or without disclosing to either the trial team or other workshop participants. Men undergoing a routine one-week HIV test were considered inappropriate for referral until such time as they knew the test result. Unlike other behavioural intervention trials, English language competency was not a requirement as this would have denied participation to a significant minority of clinic attenders (Choi *et al* 1996; Kamb *et al.* 1998a; Peterson *et al.* 1996; Shain *et al.* 1999).

## **5.7 Sample size, interim analysis and stopping rules**

The sample size for the trial was based on detecting a difference between trial arms in: 1) reattendance with a new STI during the 12 month follow up period, and 2) self-reported high-risk sexual behaviours, specifically, UAI. At the time the trial was being designed, a longitudinal study of homosexually active men in England and Wales observed that approximately 50% reported having had UAI at least once in the last month (Weatherburn *et al.* 1992). Clinical audit from the Mortimer Market Centre indicated that 20% of men presenting with an acute STI, presumed to be homosexually acquired, reattended within a year with a new infection. The sample size was calculated to be adequate to detect a two-

fifths reduction in the proportion of men reporting UAI in the last month from 50% to 30% or less, and a three-fifths reduction in the proportion of men reattending within one year with a new STI from 20% to 8%, with over 80% statistical power at the 0.05 significance level. The aim was to recruit 346 men, assuming a loss to follow up of 25% at the 12 months.

There were no planned interim analyses and no explicit provisions for stopping the trial early. All outcome and questionnaire analysis was undertaken only after the final questionnaire follow up and clinic record review and postal urine survey were all complete.

## **5.8 Blinding**

Blinding in behavioural intervention trials is difficult, because obtaining informed consent requires explaining the intervention and control conditions, and most participants will notice whether they receive other than routine care (Stephenson & Imrie 1998). This trial was 'open' or 'unblinded', however steps were taken to reduce the possible negative effects of this (Moher *et al.* 2001; Schultz 1995; Stephenson & Imrie 1998). These included using objectively determined biological outcomes as the main trial endpoints and having a second statistician, unaware of the participants' allocation, perform the main analysis (Moher *et al.* 2001; Schultz *et al.* 2002). No specific attempt was made to assess whether these measures were successful, although the 'unblinded' re-analysis of the outcome data undertaken by the candidate (JI) in preparing this dissertation yielded the same results.

## **5.9 Randomisation and recruitment**

### *Sequence and concealment*

Randomisation was stratified by clinic (Clinic 1 = Mortimer Market Centre Men's routine GUM clinic and Archway Sexual Health Clinic and Clinic 2 = Axis Clinic). The small number of men referred from Archway Sexual Health Clinic were treated as patients from Clinic 1 because they had to attend the Mortimer Market Centre to complete the trial



enrolment formalities, and because they originally presented in a routine GUM service rather than a special service like the Axis Clinic's young gay men's service. The method of randomisation was permuted blocks, varied between 4 and 10. The first study statistician who generated the randomisation schedule did not contribute to any of the main outcome analysis (Schultz & Grimes 2002). Participants had an equal probability of being assigned to either trial arm.

The only non-random allocations were regular male partners/boyfriends of men already enrolled in the study. These men were automatically assigned to the same treatment condition as their partner, who had already been randomly assigned. This was done to prevent dilution or potential contamination that might have occurred if a couple had been assigned to different trial arms. When partners were allocated to the intervention, both were invited to attend, but requested to do so on separate occasions.

Individually numbered letters in opaque envelopes explained the participant's trial assignment. These were prepared by the first study statistician and held by the study administrator. Trial arm allocation was revealed only after the participant had given written informed consent and completed the baseline questionnaire. Trial recruiters were unaware of participants' allocation until this point as well.

#### *Recruitment and implementation*

Gay and bisexual men deemed appropriate for the trial by clinic staff were given an information leaflet (see Appendix 7) and referred to one of the trial recruiters. The recruiters in turn explained the reasons for the trial, the procedures involved, and gave the potential participant an opportunity to ask questions. Additional care was taken at the recruitment stage as there was no pre-group interview and it was felt that extra time spent at this point

would help ensure attendance at the workshops and good compliance with the questionnaire follow up.

The candidate (JI) recruited a very high proportion of the trial participants (75%; 257/343).

Therefore to ensure participants' safety and the integrity of the research, informed consent forms were always completed with a different member of the clinic staff, without the recruiter present. Participants also completed the baseline questionnaire alone and in private, in a separate room, after which the recruiter gave them the envelope containing the allocation letter. Participants were asked to read the letter aloud and to show it to the recruiter.

Depending on allocation, at this point the recruiter either discussed arrangements to attend the BIG Project Workshop or, explained other prevention services available in the clinic and in either event, answered any questions the trial participant had.

#### **5.10 Intervention and control conditions**

The theoretical background and content of the BIG Project Workshop were described in detail in the previous chapter. This section describes the control condition only and the practical implementation of the intervention during the trial. All participants received the standard management (the Control condition) and only Intervention participants were invited to attend the BIG Project Workshop.

##### *Standard management – Control condition*

All of the clinic's health care professionals are trained in sexual health promotion and HIV prevention in relation to their clinical roles. Behavioural change interventions are the specific responsibility of Health Advisors and clinical psychologists.

The clinic's standard management normally occurs on the first presentation during a clinical episode of care. Standard management for a routine male attendance in each of the clinics

involves a consultation with a physician, including a sexual history, physical examination, appropriate screening for prevalent infections, the offer of an HIV test, treatment, follow up and referral to other services as necessary. In addition, according to clinic protocol, 'all high-risk gay and bisexual male attenders', and therefore by definition, all men who would be eligible for referral to the trial, normally see a health advisor for a brief counselling session (Mortimer Market Centre 1998). The content of this counselling session is determined by the client's individual circumstances. For example, in the case of a gay man diagnosed with an acute STI, the counselling discussion would normally focus on partner notification issues, which is a clinic requirement in accordance with existing legislation (National Health Service 1974). Similarly, 'All gay and bisexual men reporting unprotected anal intercourse with a partner(s) of unknown or discordant HIV sero-status or considering an HIV test should be strongly urged to consult one of the Health Advisors' (Mortimer Market Centre 1998). For all clinic attenders who, '...feel anxious about their risk of STI/HIV infection' the offer of '... seeing a Health Advisor/counsellor is recommended', but this is not required (Mortimer Market Centre 1998). Therefore, based on clinic protocols already in place, more than four out of five men referred to the study would have undergone a brief counselling session as part of their standard management, and it was not necessary nor practical to ask them to submit to further counselling.

In addition to dealing with an individual's specific issues, the brief counselling session would also normally include a discussion of other clinic services available and referral options to 'out of clinic' services. These included referral to:

- The Health Advisor team for ongoing one-to-one counselling outside of the actual clinic;
- Community-based services for issues relating to assertiveness training or identity development;
- The clinical psychology team for specific issues such as unsafe sexual practices, substance misuse, obsessive compulsive disorders; or

- The existing groupwork intervention ‘Changing personal sexual practice’ which continued to run on the same self-referral basis while the trial was in progress (Mortimer Market Centre 1998; Wanigaratne *et al.* 1997).

#### *BIG Project Workshop - Intervention condition*

Following randomisation and before leaving the clinic, participants allocated to the intervention selected a convenient date to attend the Workshop. With workshops running at approximately three week intervals it could be as long as 9 weeks between randomisation and attendance at the intervention. Participants who failed to attend on the first occasion were given two further opportunities to do so. After three attempts they were categorised as ‘treatment failures’, but retained in the cohort and followed up like all other participants. The BIG Project workshops ran on Saturdays, at approximately three-week intervals, between January 1996 and November 1997. Participants received an introductory pack in advance of the workshop that included directions and contact details for the venue, the names of the facilitators, a plan for the day, an outline of the workshop programme and a copy of the BIG Project Workbook. Trained facilitators delivered the intervention in a single session (7 hours), in a seminar room in a non-clinical area of the Mortimer Market Centre. The candidate (JI) oversaw all the logistical requirements for the workshops. All materials generated in the workshop, for example flipcharts, participant drawings and questions, were retained as part of quality assurance evaluation.

#### **5.11 Ethical approval**

Ethical approval for all aspects of the trial was obtained from the Joint University College London/University College Hospital Committee on the Ethics of Human Research (see Appendix 8). Enhancement activities to improve the quality and reliability of the main trial outcome measurements were approved by Chairman’s action in one case, and by the Services

Commissioning Information System (SCIS) Steering Group on behalf of the North Thames Regional Genitourinary Medicine Clinical Directorate in the other.

### **5.12 Ascertainment of trial outcomes**

Baseline self-reported data were collected in the clinic. Follow up data were provided primarily by postal questionnaires at 6 and 12 months. Biological outcome data were obtained through a record review of the Mortimer Market Centre's diagnostic, microbiology and virology databases and patient clinical notes.

#### *Primary outcomes*

The advantages and limitations of different STI and HIV outcomes, that is incident vs. prevalent infections, have been discussed extensively (Aral & Peterman 1996; Aral & Peterman 1998; Celentano *et al.* 2000; Cowan & Plummer 2003; Kamb *et al.* 2000; Peterman *et al.* 2000; Stephenson *et al.* 2000). In this trial, four approaches were used to ensure data on STI acquisition and treatment (incident infections) during the follow up period were as complete as possible. The four approaches were:

- 1) Review of Mortimer Market Centre and Archway Sexual Health Clinic's clinic and laboratory records for recorded diagnoses of STI and HIV and attendances;
- 2) Participant self-reports of STI treatment;
- 3) A cross-sectional postal urine survey of all participants at the end of the trial to estimate the level of prevalent undiagnosed urethral gonorrhoea, chlamydial and HIV infections; and
- 4) Matching participants to a regional database of diagnoses and attendances at other London GUM clinics to estimate the frequency of STI diagnoses and treatment at other facilities during the follow up period.

**Figure 9:** Chronological sequence of the main elements in the RCT (September 1995–November 1998)

Timetable of the RCT evaluation	1995		1996						1997							1998				1999
	Sep - Oct	Nov - Dec	Jan - Feb	Mar - Apr	May - Jun	Jul - Aug	Sep - Oct	Nov - Dec	Jan - Feb	Mar - Apr	May - Jun	Jul - Aug	Sep - Oct	Nov - Dec		May - Jun		Nov - Dec		May - Jun
Trial design, preparation & training (facilitators, recruiters, materials)	●																			
Recruitment begins	●																			
Pilot study	●	●																		
Main Trial			●	●	●	●	●	●	●	●	●	●	●	●						
Single session Workshop format			●	●	●	●	●	●	●	●	●	●	●	●						
6 month follow up					●	●	●	●	●	●	●	●	●	●		●				
12 month follow up							●	●	●	●	●	●	●	●		●		●		
Clinic record review																		●		●
Postal Urine Survey																		●		●
Main Analysis																				●

At the end of the questionnaire follow up, a research nurse and the candidate (JI) reviewed each participant's clinic record. The reviewers independently recorded all the attendance dates, diagnostic tests requested, results and the reported diagnoses (KC-60) for each participant over the 12 month follow up. Virology laboratory test requests and results were also reviewed to obtain participants' most recent HIV test results. The hand-recorded results were double-entered on computer, compared and discrepancies resolved by consulting the patient's clinical notes. Using only the patient's clinic number and study identifier ensured both reviewers remained 'blind' to participants' allocation. Self-reports of STI treatment were obtained at each follow up and compared for reporting accuracy with the review data from the clinic databases.

Two more data collection exercises were undertaken to ensure the most complete picture of STI acquisition and treatment possible, and to determine whether the clinic record review results were likely to have been affected by any systematic ascertainment bias. The first of these involved a cross-sectional postal urine survey. STI and HIV screening were not part of the original protocol, and therefore a cross-sectional postal urine survey of all participants at the end of the trial was undertaken to estimate the level of prevalent undiagnosed urethral gonorrhoea, chlamydia and HIV infection among all participants. Returned unlinked anonymous samples were tested by ligase chain reaction (LCR) (Abott Labs, Chicago IL) for *Nisserria gonorrhoea* and *Chlamydia Trachomatis* and for HIV antibodies (Connell *et al.* 2000).

The second enquiry aimed to estimate the frequency of STI diagnosis and treatment at other clinics in London. All available study participants were matched for attendances, screening and diagnoses at other London GUM clinics using a large database incorporating anonymised person-based data on more than 260,000 attendances, over a three-year period at 23 of the 32 GUM clinics in the capital (Service Commissioning Information System

(SCIS)) (Griffin *et al.* 1999). Participants were matched on four of five possible criteria: sex, ethnicity, date of birth, first half of their postcode, and how diagnosed STI was most likely acquired. The SCIS database does not contain data from every London GUM clinic; however, it does include all of the clinics with a high proportion of gay and bisexual male attenders (Personal Communications: Maria Griffin, Department of Social Science and Medicine, Imperial College of Science, Technology and Medicine, April 1998).

### *Secondary outcomes*

Whereas the primary trial endpoints were derived exclusively from objective data sources, the secondary trial outcomes relied almost entirely on participant self-reports in the study questionnaires. Where possible the quality of these measures was enhanced by use of internal consistency items. In some cases the self-reported results were also validated based on comparison with routine clinical audit data. A total of five questionnaires were developed, all based on a single proforma – Baseline, 2 follow up forms, an intervention impact form (only completed by intervention participants) and an abbreviated non-responders form (see Appendix 9). Socio-demographic data was only collected at baseline. All questionnaires used the same form and where necessary time-appropriate text alterations were made to reflect the periods being measured.

### **5.13 Description of participant questionnaires**

The participant questionnaire was divided into three sections (see Appendix 9). The first section covered demographic items, sexual history, HIV/STI risk behaviours and STI history. The second focused on STI and HIV risk knowledge, and the third consisted of a battery of six attitudinal and psychometric measures. Where possible, appropriate validated items from other survey questionnaires were used to ensure comparability of data and external validity. This was particularly the case in respect to the socio-demographic characteristics and sexual behaviour measures, where reliable items have been developed in



previous research studies (Bradford 1997; Hickson *et al.* 1994; Johnson *et al.* 1994; Nardone & Mercey 1995; Office of Population and Censuses and Surveys 1991; Ostrow *et al.* 1993; Thornton & Catalan 1993; Woody *et al.* 1996). The choice of attitudinal and psychometric scales was based on a review of the current literature on intrapersonal factors and variables associated with high risk sexual behaviour and inconsistent condom-use, and guidance from the clinical psychologists within the study team (Gold 1993; Gold *et al.* 1991; Gold & Skinner 1993; Gold & Skinner 1992; Horn & Chetwynd 1989; Thornton & Catalan 1993). Figure 10 describes each of the attitudinal and psychometric scales used, and its validity and contribution to the trial's overall dataset. Nearly all of the instruments were validated scales commonly used in other health settings, or instruments specifically intended and validated for use in gay and bisexual men (Hays *et al.* 1990; Shah *et al.* 1997; Wanigaratne *et al.* 1997). All of the attitudinal and psychometric measures were completed at baseline, 6 and 12 month follow up with the exception of the General Health Questionnaire (GHQ-12), which was completed at baseline only. An Intervention Impact Questionnaire that included only the attitudinal and psychometric scales from the baseline questionnaire was completed by participants immediately after the workshop, and analysed as part of the process data at the end of the study. The 'non-responders' form, which contained only socio-demographic items, was offered to men referred to the trial but who declined to participate.

#### **5.14 Statistical methods in the main outcome analysis**

The plan of the main outcome analysis was based on all randomised participants regardless of whether they completed the intervention or follow up questionnaires (intention to treat) (Pocock 1983). Only the non-randomised participants, that is, the small number of partners who were allocated to the same arm as their randomised partner, were excluded from the main outcome analysis. Analysis of the STI outcomes was based on cumulative proportions

**Figure 10:** Description, validity and contribution of each of the attitudinal and psychometric measures used in the participant questionnaires

Scale and key reference	Description	Validity	Function in trial
<b>General Health Questionnaire (GHQ-12)</b> (Goldberg <i>et al.</i> 1976)	Short form 12 item scale designed to detect psychiatric disorder in community & non-psychiatric settings	Validated in many different non-psychiatric settings, but not specifically with gay men	Used at baseline <i>only</i> to ensure no differences in psychiatric symptoms between trial arms
<b>HIV-related Attitudes questionnaire (HAQ)</b> (Hays <i>et al.</i> 1990)	Composite instrument made up of 10 brief scales (26 items) measuring attitudes & self-perceptions relating to safer sex	Original validation with young gay men in US, subsequently used with UK gay men (Gilbart <i>et al.</i> 2000)	Predictive measure to link attitudes & behaviour & consistency check for other scales measuring similar constructs
<b>Rosenberg Self-Esteem scale</b> (Rosenberg 1965)	10 item scale measuring self-esteem as a single construct	Validated, robust, effective and efficient, although not validated with gay men (Bowling 1991)	Used as intermediate measure of impact of workshop sessions relating to self-esteem
<b>'Readiness to change' questionnaire</b> (Rollnick <i>et al.</i> 1992)	12-item scale based on Prochaska & DiClemente's model. Determines respondent's stage in the model	Validity and reliability demonstrated in other health fields. Not validated for sexual behaviour change	Assign participants to a 'stage' at baseline & then confirm movement through stages over follow up
<b>Situational Self-confidence questionnaire (SSCQ)</b> (Wanigaratne <i>et al.</i> 1997)	Measure of individuals' self-confidence to perform safer sex or avoid sex in 7 scenarios	Original validation with men attending 'Changing personal sexual practice' intervention	Repeated measurement could explain effect of individual sessions of the workshop
<b>Sexual Risk Cognitions questionnaire</b> (Shah <i>et al.</i> 1997)	A 22-item scale assessing type & frequency of cognitions associated with unsafe sex	Validated with UK gay men. Strong correlations between items and self-reported sexual behaviour	Link changed cognitions & self-reported sexual behaviours between baseline and follow up

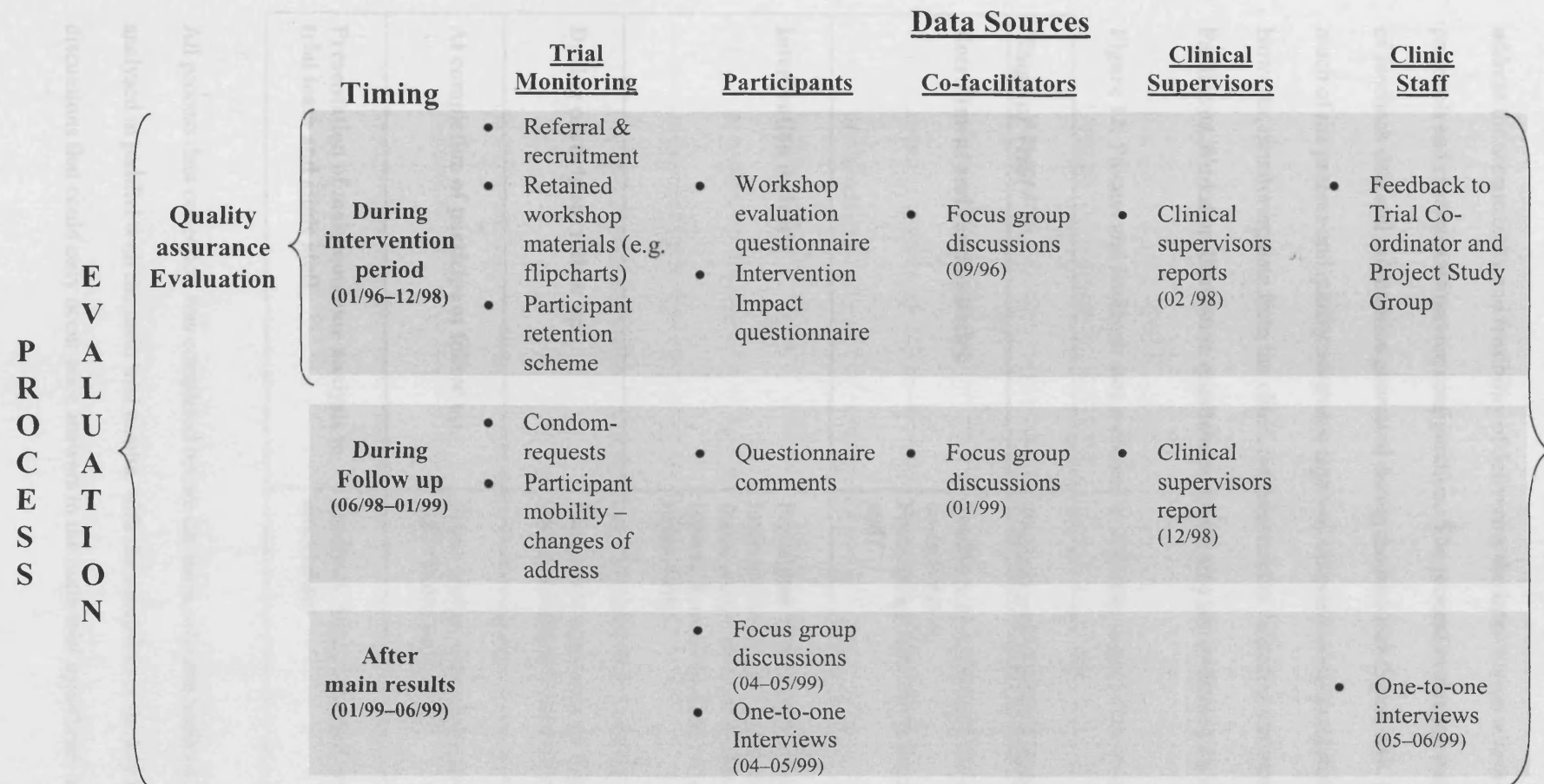
in each trial arm, from baseline to the end of the 12 month follow up, re-attending the clinic with a new STI diagnosis or a new clinical episode. Data from the sub-studies were only used to confirm the findings of the record review and to assess any ascertainment bias. For the secondary sexual behaviour outcomes, comparisons in the main analysis included reported behaviour during the last-month at baseline, 6 and 12 month follow ups, and during the last year at baseline and 12 month follow up. Attitudinal and psychometric scales were measured at baseline, and compared at 6 and/or 12 month follow up using between arm, 'within-arm' and 'within-individual' comparisons from baseline.

Appropriate statistical analysis techniques for randomised clinical controlled trials were employed (Moher *et al.* 2001; Pocock 1983). For unadjusted comparisons between trial arms, chi-squared ( $\chi^2$ ) tests were used for binary data and Mann-Whitney tests for continuous data. For 'within-arm' and 'within-individual' changes, Wilcoxon signed rank test and McNemar's chi-squared test for matched observations were used. Crude and adjusted odds ratios with 95% confidence intervals were used for the main STI and selected behavioural outcome measures. Adjustment for possible baseline confounding factors was performed through logistic regression. The only *a priori* sub-group analysis planned was an 'on treatment' analysis, comparing those participants who actually attended the workshop with the controls.

### **5.15 Process and quality assurance evaluation**

An evaluation to assess the processes involved in the trial, and the quality and fidelity of the intervention delivery, was carried out alongside the main trial and analysed alongside the main trial results (see Figure 11). The aim was to obtain explanatory information about the intervention's performance in the field and to ensure that the intervention was delivered as

**Figure 11:** Plan and chronological sequence of the components of the process and quality assurance evaluation (October 1995–June 1999)



planned, and consistently in each workshop (Kamb *et al.* 1996; O'Leary *et al.* 1997; Wight & Obassi 2003). In the context of a pragmatic trial, the process evaluation also needed to address the acceptability and feasibility of delivering the intervention within existing clinic protocols and current staff/service configuration. The process evaluation emphasised the use of feedback data and information generated during the trial (see Figure 12). By its nature, much of the process and quality assurance data was obtained using qualitative methods. However, monitoring data from the clinic, the Intervention Impact questionnaires and Participant Workshop Evaluation questionnaire were also incorporated (see Appendix 9).

**Figure 12:** Process and feedback data collected at different stages of the trial

<b><i>Stage of Trial</i></b>	<b><i>Process and feedback data</i></b>
<b>Recruitment and randomisation</b>	Feedback on training of recruitment staff and co-facilitators Focus group with recruitment and clinical staff
<b>Intervention delivery</b>	Participant Workshop Evaluation & Intervention Impact questionnaires; focus groups with workshop co-facilitators; reports from co-facilitators' clinical supervisors
<b>During participant follow up</b>	Participant comments on follow up questionnaires and condom-request sheets
<b>At completion of participant follow up</b>	Focus groups with intervention and control participants separately
<b>Presentation of main outcome analysis to trial team and clinic staff</b>	Feedback from clinic staff and key informant discussions

All process data collection was completed before the main outcome analysis began, and analysed in parallel with the main trial results, with the exception of the key informant discussions that could only occur once answers to the main trial hypotheses were available.

### *Qualitative and feedback data collection*

All clinic staff and Health Advisors who undertook either trial recruiter or facilitator training were given the opportunity to feed back on the training formally, through their clinical supervisors and training evaluation sheets and, informally, through discussions with the candidate (JI) and members of the BIG Project Study Group (see section 5.16).

Two focus groups with the facilitators took place during the main trial. They covered the different sessions of the workshop and delivery of specific sessions, adequacy of the training and supervision, and implications of implementing the workshop into the routine clinic services. Six participant focus groups, three each with intervention and control participants, were scheduled at approximately 6 month intervals, such that they coincided with the time when most men completed the 12 month follow up. For obvious reasons intervention and control participant focus groups used slightly different topic guides. For example, intervention participants discussed perceptions of the intervention, recall of individual sessions and identification of any lasting impact of the intervention. Control participant focus groups, on the other hand, dealt with the experience of being involved in research without receiving the actual intervention, perceptions of what they may have missed by not receiving the intervention and the value of ongoing contact with the trial team. All of the participant focus groups discussed whether being involved in sexual behaviour/STI/HIV research had any influence on their sexual behaviour practice, and how they reported this information to the trial team. All focus groups were conducted by an external facilitator, tape-recorded and transcribed verbatim.

Other feedback data came from two reports by the clinical supervisors that dealt firsthand with the co-facilitators' experiences of running the workshops. Trial participants also provided substantial spontaneous feedback in the comments sections of the study questionnaires and

condom-request forms. These were recorded throughout the trial and reviewed as part of the process evaluation.

#### *Quantitative and monitoring data*

The number and eligibility of men referred from the clinic, condoms distributed and change of address were all monitored throughout the trial. Data from non-responders questionnaires provided basic socio-demographic data that were compared to the data from study participants (see Appendix 9).

Participant Workshop Evaluation and Intervention Impact questionnaires were completed at the end of the day. These were used primarily to assess the quality and fidelity of the intervention delivery and to gauge participant perceptions of the facilitators' performance in the workshops.

#### *Analysis of the process and quality assurance data*

Analysis of the process and quality assurance data involved a variety of different approaches according to the type of data, its quality and the questions being addressed. All of the process data was coded and analysed separately from the main outcome data in order to answer distinct questions, for example about acceptability and feasibility. This approach also facilitated the generation of additional explanations for the trial results that were explored in a secondary analysis. The results of this analysis are presented later in the thesis in Chapter 8.

### **5.16 BIG Project Study Group**

In addition to the main group of investigators, a BIG Project Study Group was convened to assist with the logistics and practicalities of running this complex trial. The BIG Project Study Group included members of the Department of Sexually Transmitted Diseases as well as key representatives from all the professional groups in the GUM clinics. The BIG Project

Study Group met regularly and advised on both methodological and practical issues.

Appendix 10 details the full membership of the BIG Project Study Group.

### **5.17 Conclusions**

In order to adequately test the main trial hypotheses and demonstrate the effectiveness of the BIG Project workshops, the RCT evaluation needed to meet five essential requirements. The trial methodology and linked process and quality assurance evaluation were intended to address all of these. The trial design itself is an important addition to existing work on HIV prevention evaluation because it based the sample size and main trial outcomes on objectively determined measures of STI acquisition and treatment. In any future decisions about implementation of the intervention in routine GUM services, the impact on STI would be considered to provide the most persuasive evidence of effectiveness. In this way, the study design and trial methods set a benchmark for the level of rigour achievable in individually randomised behavioural intervention trials (Personal Communication: Wayne D Johnson, Cochrane Review Group for Behavioural Interventions for HIV Prevention, Centers For Disease Control and Prevention, Atlanta, GA, August 2003).



## **Chapter 6**

### **Implementation, process and quality assurance in the trial**

#### **6.0 Introduction**

The next two chapters describe in detail the conduct and results of the RCT. This chapter is concerned with implementation of the trial and the intervention, and the next deals with the main results of the trial. This chapter addresses four questions relating to the conduct, quality and acceptability of the intervention, and the integrity of the trial. These are:

1. Was it possible to implement the trial and deliver the intervention as outlined in the original research protocol?
2. Did the intervention reach its target population of high-risk gay men attending GUM services?
3. Was it feasible and acceptable to implement the RCT within routine clinic services?
4. Was the intervention delivered consistently to all participants?

## **6.1 Pilot Phase**

A pilot phase of the trial was undertaken in advance of the main study, and the results provide an answer to the first question. The pilot phase lasted approximately five weeks (September/October 1995). The purpose of the pilot phase was to ensure all the different components of this complex trial worked as planned and, specifically, that the intervention could be delivered as intended and described in the original protocol (see Appendix 5). The pilot phase involved running two BIG Project workshops using different delivery formats. Two delivery formats were used. One that consisted of three sessions (two evening sessions and weekend day) and a second consisting of two longer sessions (two weekend days). The reason for piloting the intervention in two different delivery formats was to see which one was more acceptable to participants and facilitators.

The BIG Project Study Group, first convened during the trial's development stage, contributed substantially to interpreting the pilot phase and responding to the issues raised by this part of the evaluation.

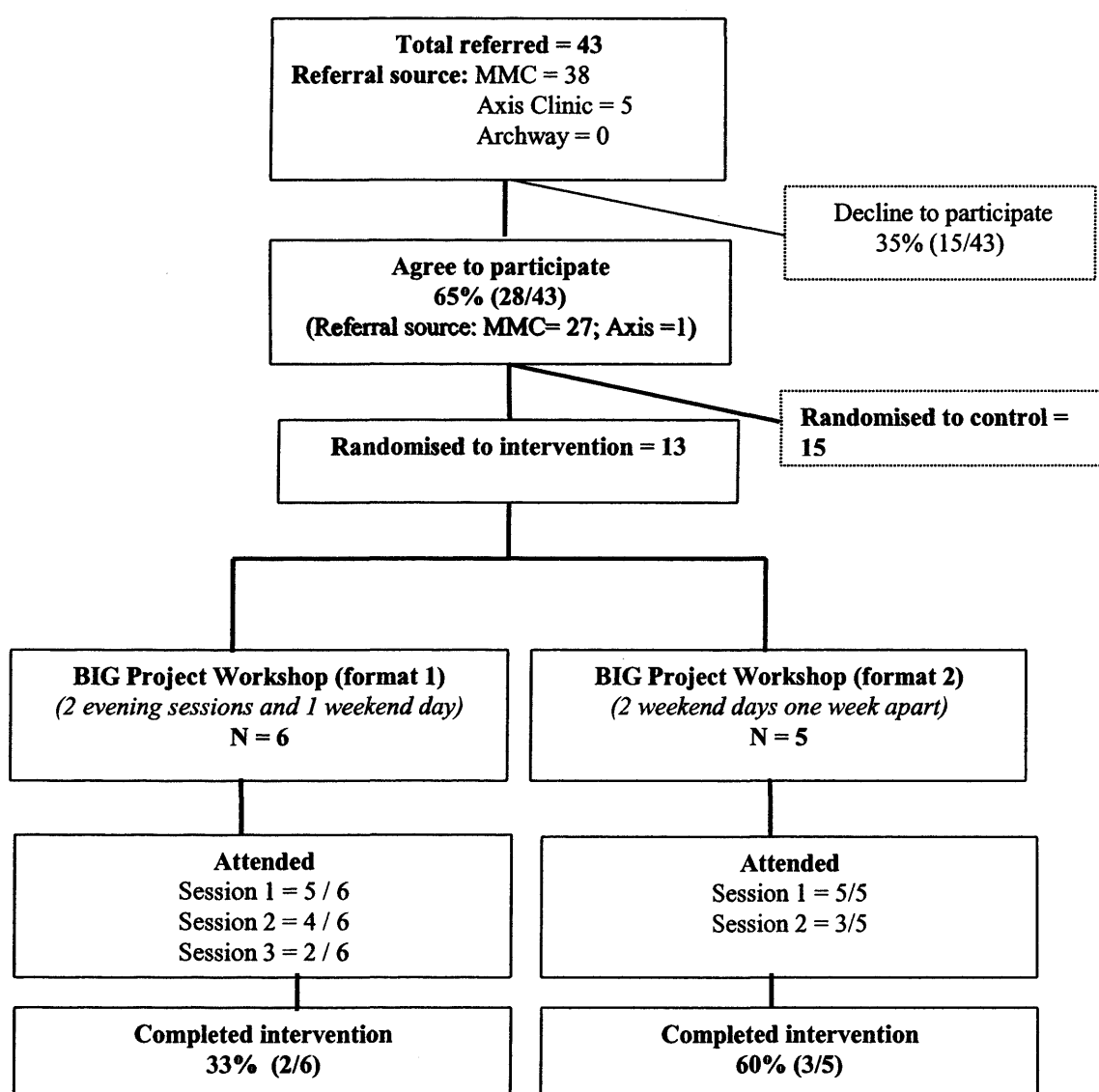
### *Questionnaire piloting*

All potential questionnaire items were collated and pre-tested with respondents from the Mortimer Market Centre's men's GUM clinic during the trial's development stage. Questionnaire pre-testing aimed to determine average completion time and identify any difficult or confusing items (see Appendix 9). Following the first pre-testing, a number of items were modified, and the revised questionnaire was re-tested on a further 20 clinic attenders. No specific difficulties were recorded among men completing the revised questionnaire, and this became the proforma for all subsequent versions (see Appendix 9).

### *Referral, recruitment and attendance*

Figure 13 describes the flow of participants during the pilot phase. In total, 43 eligible men were referred to the study, and 28 agreed to participate (Response rate = 65.1%). Sixty-eight percent (29/43) of referrals came from clinic nursing staff, 21% (9/43) from doctors and 11% (5/43) from Health Advisors. Two-thirds of men referred to the trial discussed the study with one of the clinic recruiters and the remainder with the candidate (JI). More than half of men referred to the study had had an acute STI diagnosed in the clinic during the current episode of care. Of the 15 men referred to the trial who declined to participate, 12 (80%) agreed to

**Figure 13:** Participant flow during the pilot phase of the trial



complete a non-responders' questionnaire. The most common reason for declining to participate was 'have a regular weekend commitment (e.g. work) that makes it impossible to attend'.

Of the 28 men recruited to the study, 13 (46%) were allocated to the Intervention condition and 15 to the Control condition. Two men allocated to the intervention were unable to attend on pilot dates, but did attend a later workshop during the main study. One man randomised to the intervention, enrolled with his regular partner. Both men completed the intervention on separate occasions as required by the protocol; one attended during the pilot phase and the other during the main trial.

#### *Delivery of the intervention and between-session attrition*

Attendance at the first session of each workshop was high – only one man failed to attend. However, as Figure 13 shows, between-session attrition was very high and overall less than 50% (5/11) of randomised participants attended all sessions. Some attrition between sessions had been anticipated based on the experience of 'Changing personal sexual practice', but the rate in the pilot phase was much higher than expected and a cause for concern (Williams *et al.* 1993). The plan in the pilot phase had been to test two different formats (3 vs. 2 sessions) to determine which was more acceptable. However, with unacceptably high between-session attrition in both delivery formats, it was clear that delivering the BIG Project Workshop in a multiple-session format was not viable for the main trial.

The two pilot workshops were run by different co-facilitators. Minor time adjustments were made to accommodate the different delivery formats (3 vs. 2 sessions), but the actual sequencing of exercises was preserved (see Figure 6). Neither team of facilitators experienced any problems delivering the intervention or managing the groups. Following the workshop, the two teams of facilitators prepared short written reports summarising their

experiences, indicating which exercises, if any, might be dropped, and detailing any participant feedback. These reports were reviewed by the investigators and the BIG Project Study Group as part of the pilot evaluation.

*Key issues arising from the pilot phase*

Monitoring data from the clinic, combined with the co-facilitators' and clinical supervisors' reports, were used in the pilot phase evaluation. Together they highlighted three key issues that required redress before proceeding to the main trial:

- 1) Too few eligible men from the clinics were being referred to the trial;
- 2) The lengthy informed consent and enrolment procedures limited the clinic staff's availability to recruit even those men who were referred;
- 3) Between-session attrition indicated that a multi-session intervention was not acceptable to the target population and would not be viable in the main trial.

The referral rate during the pilot phase was approximately two-thirds the number anticipated in the original study protocol (see Appendix 5). This was partially due to practical issues of working in busy GUM clinics. Referral relied heavily on the doctors, who constantly move between clinics within the Mortimer Market Centre, and who are asked to refer patients to numerous ongoing studies at the same time. When the doctors were asked about their referral of patients to this study, some said that they were not sufficiently well acquainted with the trial – of its starting, of the eligibility criteria, of the appropriate time in the consultation to make the referral and to which member of staff eligible patients should be referred. Others worried that taking time to discuss the study with patients would disrupt the flow of the consultation which would delay them finishing, when they had to go on to another clinic elsewhere within the service. Similar comments came from other staff groups. They suggested more promotion of the trial and additional explanation to staff were needed in order to develop

staff confidence in undertaking the initial pre-referral discussion with potentially eligible patients.

In the pilot phase, enrolment of participants was undertaken by a small number of specifically trained nurses. The relatively complex explanation, consent and enrolment procedures meant that these staff had to be away from their normal duties for between 20 and 40 minutes with each potential trial participant. This was unacceptable to clinic managers, and impossible during very busy periods. To increase referral and recruitment, dedicated study staff were needed in the clinic, particularly during busy periods.

Three explanations for the high between-session attrition emerged. The first was that participants found it difficult to engage with the explanations of the intervention's CBT approach. This required a lengthy didactic session that occupied most of the first evening in the three-session format and a large part of the morning in the two-session format. As one participant later recounted to the candidate (JI), '... this was not what I thought the workshop would be about, and it made me feel like I was being given a problem I didn't feel like I had. And that's why I didn't come back.' The second explanation was, as some of the facilitators reported, long introductions and didactic exercises left the group 'flat' and in need of reinvigoration before moving on. As a result it sometimes felt like the workshop rather suddenly lost momentum and this had a strong negative effect on participants. The third explanation, according to some participants, was that losing people between sessions made them feel vulnerable and less inclined to join in, because they felt the confidentiality of the group had been broken by the departures. When they noticed that one or two people did not return for the next session, they felt less inclined to come back themselves, and less willing to engage with the exercises, particularly those that might involve some degree of personal disclosure.

**Figure 14: Lessons learned in the pilot phase and actions taken**

Lesson	Action
<b><i>Referral and recruitment</i></b>	
Need to increase staff and patient awareness of trial	<ul style="list-style-type: none"> <li>• Disseminate promotional materials</li> <li>• Have them available in all consulting rooms</li> <li>• Familiarise staff with content of promotional materials</li> </ul>
Need to improve staff understanding of the trial	<ul style="list-style-type: none"> <li>• Presentations in staff meetings and in junior doctors' clinic induction</li> <li>• Provide monthly progress updates</li> <li>• Develop incentives for staff referring patients to the trial</li> </ul>
Need to help identify appropriate point in clinical consultation to discuss study	<ul style="list-style-type: none"> <li>• Implement procedural protocols for specific clinic scenarios (e.g. HIV testing)</li> </ul>
Need to ensure as many eligible patients as possible are referred to the trial	<ul style="list-style-type: none"> <li>• Ink-stamp in patients' clinic notes indicating eligibility and whether study discussed.</li> <li>• Incentive scheme for clinic staff.</li> </ul>
Need to identify designated referral and enrolment staff and support other recruiters	<ul style="list-style-type: none"> <li>• Trial co-ordinator (JI) 75% clinic-based.</li> <li>• Designated nurse available ½ day per week</li> </ul>
<b><i>Intervention delivery and retention</i></b>	
Reduce number of workshop sessions.	<ul style="list-style-type: none"> <li>• Intervention reduced to one-day format</li> <li>• Comprehensive workbook developed to accompany workshop (see Appendix 3)</li> </ul>
Increase numbers attending by reducing frequency of workshops	<ul style="list-style-type: none"> <li>• Workshops scheduled to run three-weekly rather than bi-weekly</li> </ul>

### *Responding to the pilot phase*

Figure 14 illustrates the key lessons learnt in the pilot phase and actions taken to address them. New referral and recruitment guidance and new enrolment procedures were introduced. These aimed to raise awareness of the trial to all clinic staff (doctors, nurses and health advisors), increase motivation to refer patients and ensure recruiters were always available to enrol participants. Additional promotional materials were placed in the clinics and in all the doctors' consulting rooms. Regular study updates were instigated as part of the weekly clinic meetings and a referral incentive scheme introduced. The trial coordinator/candidate (JI) was available to undertake referral discussions and complete participant enrolment during busy periods and routinely covered in the weekly Axis Clinic. A member of the nursing team was also employed by the BIG Project to be available at other times.

The intervention was reformulated in response to pilot findings. The final format of the intervention is described and illustrated in Chapter 4 (see Figure 6). The facilitators' reports and the participant feedback both recommended that the intervention be shortened, ideally into a one-day format. They also suggested that the interactive and role-play exercises be enhanced and that the didactic material be restricted to discussion in the participant workbook (see Appendix 3). Intervention facilitators and clinical psychologists from the BIG Project Study Group recommended that a measure be introduced to assess the relative effectiveness of the single-session format compared to multiple sessions. An Intervention Impact questionnaire consisting of four attitudinal and psychometric scales from the baseline questionnaire was implemented in the main trial. The aim of this questionnaire was to obtain additional reassurance that the single-session format performed as well as the multi-session format described in the original protocol, and that it achieved its intended objectives (see Section 6.4).



## *Summary*

The pilot phase helped the investigators to understand better the limits of what was possible in the clinic without providing additional dedicated support. It made clear that to optimise the research design, achieve the sample size and follow up rates, the intervention had to be revised. It also demonstrated that the referral and recruitment processes needed to be simplified for clinic staff. Introducing the single-session workshop format was essential to achieve an adequate completion rate for the trial results to be meaningful and generalisable to other GUM settings. Arguably, this was a substantial deviation from the original 'Changing personal sexual practice' intervention. However, the BIG Project Study Group generally agreed that an intervention as lengthy and complex as 'Changing personal sexual practice' would not be practical or feasible in routine clinic practice. In the context of a pragmatic trial, this was an important finding in its own right. Only if the intervention was acceptable to the target group and feasible to deliver within the existing clinic routine could it be expected that it would be widely adopted. Borrowing from the language of phase I and II clinical treatment trials, it could be argued that the most important result of the pilot phase was to demonstrate that a single-session intervention represented the 'maximum tolerated dose' acceptable to the target population of gay men attending GUM services (Stephenson & Imrie 1998).

## **6.2 Reaching the target population**

The second question set out in the introduction asked, did the intervention reach its target population of high-risk gay men attending GUM services? To answer this, trial monitoring data, routine clinical data and questionnaire data from non-responders and all randomised participants were compared.

In total, 499 men, who met at least one of the eligibility criteria, were referred to the study, and 343 (68.7%) were randomised. Here, the randomised men are compared to 138 men who

declined to participate and completed a non-responders questionnaire, and also to all gay and bisexual men attending the Mortimer Market Centre's GUM clinics. These results are then examined in comparison to routine surveillance data and other relevant research findings.

### *Socio-demographic characteristics*

Of men recruited to the study, 85.7% (294/343) were referred from the Mortimer Market Centre routine men's GUM service, 12.5% (43/343) from the Axis Clinic and 1.7% (6/343) from the Archway Sexual Health Clinic. Diagnosis of an acute STI was the most frequently recorded eligibility criterion. There were no significant differences between men who chose to join the study and those who declined according to their eligibility criteria (see Table 3).

**Table 3:** Eligibility criteria for all randomised study participants and those who declined to participate

	<b>All randomised participants (N = 343)</b>	<b>Declined to participate (N = 138)</b>	<b>p value comparing those who declined &amp; all randomised participants</b>
<b>Acute STI</b>	<b>49.8%</b> (171/343)	<b>55.0%</b> (76/138)	0.300
<b>UAI in last 12 months</b>	<b>40.8%</b> (140/343)	<b>39.9%</b> (55/138)	0.846
<b>Expressed concern about sexual practices</b>	<b>9.4%</b> (32/343)	<b>5.1%</b> (7/138)	0.122

Routine socio-demographic and clinical data on all gay and bisexual male GUM attenders at Mortimer Market Centre (N = 4690) during the recruitment period (October 1995 to November 1997), on recruited participant and non-responders were compared to assess the overall representativeness of the study population.

Overall the study population was similar to other gay and bisexual men attending the Mortimer Market Centre (see Table 4). Men enrolling in the trial were for the most part self-identified as gay or homosexual, predominantly 'white' and slightly younger than other clinic users. Comparing those who agreed to participate and those who declined, there were some notable differences. Those who declined to participate were somewhat more likely to self-identify as being of ethnic minority origin ( $p = 0.06$ ) and significantly less likely to have undertaken education or training beyond secondary school ( $p = 0.04$ ). However, it is not uncommon in UK studies of gay men to find that fewer ethnic minority men and men with lower educational attainment participate in research or health promotion activities (Fenton *et al.* 1999; Hickson *et al.* 2001).

**Table 4:** Socio-demographic characteristics of all new gay male clinic attenders at the Mortimer Market Centre (10/1995–11/1997), all randomised participants and those who declined to participate

	All new gay male clinic attenders (N = 4690)	All randomised participants (N = 343)	Declined to participate (N = 138)
<b>Sexual Identification:</b>			
Gay	95.7%	93.9%	91.2%
<b>Age:</b>			
Median (range)	31 (17–80)	29 (18–58)	29 (17–59)
<b>Ethnicity:</b>			
White	88.9%	90.6%	84.1% <sup>(1)</sup>
<b>Education:</b>			
Beyond secondary school		85.7%	77.2% <sup>(2)</sup>
<b>Occupation:</b>			
Professional or skilled non-manual <sup>(3)</sup>		56.9%	55.5%
<b>Eligibility criteria:</b>			
Presenting with acute STI		49.9%	54.9%

(1)  $p = 0.06$  as compared to all randomised participants.

(2)  $p = 0.04$  as compared to all randomised participants.

(3) Social classes I, II, III (Office of Population and Censuses and Surveys 1991).

### *Sexual behaviour and other HIV risk indicators*

Table 5 describes the baseline sexual behaviour and other HIV risk characteristics of all randomised participants and by study arm. With only one exception, there were no statistically significant differences between the two study arms suggesting that the randomisation was effective. The only significant difference was in the proportion reporting ever having had an HIV test. Overall a high proportion (79.5%; 242/342) of participants indicated that they had previously had an HIV test; the figure was 84.0% (147/175) for intervention participants and 74.9% (125/167) for control participants ( $p = 0.036$ ). These proportions were substantially higher than those observed in UK community studies and in surveys of gay men in GUM clinics in London (Hickson *et al.* 1994a; Nardone *et al.* 1998; Weatherburn *et al.* 1992). Using self-reported HIV status as a measure of prevalence in the study cohort suggested that fewer HIV-positive men than might have been expected were recruited to the trial (unpublished clinic data).

The trial population appeared similar to other UK study samples in respect to reporting of specific lifetime sexual experiences that have been shown to be predictors of HIV sero-conversion (Gilbart *et al.* 2000; Fitzpatrick *et al.* 1989a; Fitzpatrick *et al.* 1990; Ostrow *et al.* 1995; Williams *et al.* 1996). For example, the distribution of age at first homosexual contact, age at first AI and the proportion reporting a regular male partner were all similar to the rates reported in a large-scale longitudinal study of gay and bisexual men in England and Wales (Project SIGMA) (Weatherburn *et al.* 1992). In Project SIGMA, 56% described their relationship with their regular male partner as 'open', which was higher than the 40.0% (68/164) reported by the trial participants (Weatherburn *et al.* 1992).

**Table 5:** Distribution of sexual behaviour and other HIV/STI risk characteristics at baseline for all randomised participants and by study arm

	All randomised participants (N = 343) <sup>(1)</sup>	By study arm		p value <sup>(2)</sup>
		Intervention (n = 175)	Controls (n = 168)	
<b><u>Lifetime sexual experience:</u></b>				
First homosexual contact – Age – Median (range)	16 (5–38)	16 (6–31)	16 (5–38)	0.663
First AI – Age – Median (range)	20 (6–39)	20 (6–31)	20 (12–39)	0.567
Used condom at first AI (%)	38.9% (131/337)	40.1% (69/172)	37.6% (62/165)	0.632
Commercial sex (sold) in last year (%)	4.1% (14/343)	4.6% (8/175)	3.6% (6/168)	0.640
Commercial sex (bought) in last year (%)	5.3% (18/340)	5.8% (10/173)	4.8% (8/167)	0.684
Regular male partner/boyfriend (%)	48.7% (164/337)	48.5 (83/171)	48.8% (81/161)	0.962
Of whom: ‘Open relationship’ with regular partner	40.0% (68/164)	39.8% (33/83)	43.2% (35/81)	0.777
<b><u>Recent sexual partners:</u></b>				
Sexual contacts in <i>last year</i> – Median (range)	20 (0–500)	20 (1–300)	20 (0–500)	0.648
Sexual contacts in <i>last month</i> – Median (range)	3 (0–60)	3 (0–60)	3 (0–45)	0.801
AI partners in <i>last year</i> – Median (range)	4 (0–300)	3 (0–100)	4 (0–300)	0.198
AI partners in <i>last month</i> – Median (range)	1 (0–30)	1 (0–12)	1 (0–30)	0.540
UAI partners in <i>last year</i> – Median (range)	1 (0–60)	1 (0–60)	1 (0–40)	0.812
UAI partners in <i>last month</i> – Median (range)	0 (0–4)	0 (0–4)	0 (0–3)	0.171
<b><u>Most recent sexual partner:</u></b>				
Regular partner/boyfriend (%)	39.4% (135/335)	40.0% (70/175)	38.7% (65/168)	0.804

<sup>(1)</sup> Item non-response at most 8 cases for each all questions.

<sup>(2)</sup> Comparing intervention and control arms.

**Table 5: (cont'd) Distribution of sexual behaviour and other HIV/STI risk characteristics at baseline for all randomised participants and by study arm**

	All randomised participants (N = 343) <sup>(1)</sup>	By study arm		p value <sup>(2)</sup>
		Intervention (n = 175)	Controls (n = 168)	
<b><u>Recent sexual behaviour:</u></b>				
1 or more episodes of UAI in <i>last year</i>	<b>59.6%</b> (202/339)	59.9% (103/172)	59.3% (99/167)	0.910
1 or more episodes of UAI in <i>last month</i>	<b>33.4%</b> (113/338)	36.6% (63/172)	30.1% (50/166)	0.205
<i>Of men ever having had UAI (n = 295):</i>				
Last UAI with partner of unknown or different HIV status	<b>68.8%</b> (203/295)	66.0% (97/147)	71.6% (106/148)	0.296
<b><u>Sexual health:</u></b>				
> 2 previous STI diagnoses	<b>21.0%</b> (72/343)	22.3% (39/175)	19.6% (33/168)	0.548
Ever had HIV test	<b>79.5%</b> (272/342)	84.0% (147/175)	74.9% (125/167)	0.036
<i>Of men reporting previous HIV test (n = 272)</i>				
Self-report as HIV positive	<b>2.6%</b> (7/272)	2.7% (2/147)	2.4% (3/125)	0.270
Previous HIV prevention workshop	<b>14.6%</b> (50/291)	15.5% (23/148)	18.9% (27/143)	0.450
<b><u>Alcohol and drug use:</u></b>				
Drink alcohol once a week or more	<b>83.4%</b> (286/343)	81.7% (143/175)	85.1% (143/168)	0.397
Used Class A drugs in last year (e.g. crack, cocaine, heroine)	<b>36.6%</b> (124/339)	36.6% (63/172)	36.5% (61/167)	0.985
Used 'club' drugs in last year (e.g. ecstasy, acid, speed, poppers)	<b>79.9%</b> (274/343)	79.4% (139/175)	80.4% (135/168)	0.830
Ever injected non-prescribed drugs	<b>3.8%</b> (13/341)	4.6% (8/175)	3.0% (5/166)	0.452

<sup>(1)</sup> Item non-response at most 8 cases for each all questions, except previous HIV prevention workshop (84.0%; 291/343).

<sup>(2)</sup> Comparing intervention and control arms.

The proportion of study participants reporting condom-use at first AI (38.9%; 131/337) was much higher than in other UK community studies at the time (Hickson *et al.* 1996; Nardone *et al.* 1997; Weatherburn *et al.* 1992). This may reflect age distributions between the different samples and the year in which AI first occurred (Nardone & Mercey 1995; Weatherburn *et al.* 1992). For example, a community survey of gay men in London found that among men whose first AI occurred prior to 1980, less than 10% reported using condoms, while among those who reported their first AI in 1994 or later, 95% reported using a condom (Nardone & Mercey 1995).

Reported alcohol and drug use in the study population was similar to American and British longitudinal studies, although the reported use of so-called 'club' drugs was much higher (McCusker *et al.* 1990; Ostrow *et al.* 1993; Stall *et al.* 1986; Weatherburn & Project SIGMA 1992). A possible explanation for this may have been the inclusion of 'poppers' (nitrate inhalants) in this category in the BIG Project questionnaire. In the UK, the sale of 'poppers' is not illegal and some men report using 'poppers' without reporting any other recreational drug use (French & Power 1996). However, even when 'poppers' were excluded, 66.5% (228/343) reported some other recreational or 'club' drug use, which was still higher than in other UK samples (Nardone & Mercey 1995; Weatherburn *et al.* 1992).

### *Summary*

Overall, men referred to the trial appear to have been similar to gay and bisexual men clinic attenders in respect to basic socio-demographic variables, although more men from ethnic minority backgrounds, and significantly more men with lower educational qualifications, declined participation. Interestingly, in respect to specific lifetime sexual experiences, the study population was broadly similar to other gay men, but in relation to sexual behaviours and use of 'club' drugs, the study cohort appeared to be more high-risk than men recruited in other UK community surveys. Obviously, there are limits to this type of simple direct

comparison, but they do nonetheless give an overall impression of the study cohort's high-risk status relative to other populations of gay men. In relation to the original question, it seems a fair conclusion that the simple eligibility criteria for referral to the study successfully identified men at high-risk of STI and HIV infection and facilitated their being recruited, which has important implications for the ultimate generalisability of both the intervention and the trial results.

### **6.3 Acceptability and feasibility of the intervention**

In the original investigation plan, routine trial monitoring data and Participant Workshop Evaluation questionnaires were to be used to assess acceptability and feasibility of delivering the intervention within routine services. Recruitment to the main trial began in January 1996 and was planned to last for twelve months. However, because of unforeseen events, it was necessary to extend this a further ten months to achieve the necessary sample size.

Recruitment was completed in November 1997 with the last BIG Project Workshop delivered in December. The unforeseen events which necessitated the additional recruitment time included: the introduction of two new computer systems; 50% reduction in bookable appointments over a five-month period; two changes in laboratory and reporting software, and substantial staff turnover. The impact of these was considerable and consequently the trial monitoring data alone (referral and recruitment rates over time) does not provide either an accurate or adequate measure of acceptability. Therefore, other measures, principally the response rate and the attendance rate for those allocated to the intervention, were used.

#### *Acceptability*

All of the main measures of the trial's acceptability among clinic attenders are presented in Table 6. The original study research protocol estimated 120 eligible men would attend the clinics each month and that approximately 50% could be recruited to the study (see Appendix 5). During the main trial, referral rates varied between 50 men in the busiest months to only



12 during staff holidays and the introduction of new computer systems. But as the table shows the overall response rate and attendance rates were higher than expected (see Table 6).

The overall referral rate, as a proportion of all gay men clinic attenders was about 10.6% (see Table 6). Routine clinic data could not identify the number of attenders who met the trial's eligibility criteria. However, based only on those men referred to the study who spoke to a recruiter, all of the measures suggest that both the trial and intervention were highly acceptable (see Table 6).

**Table 6:** Acceptability measures of the trial among gay male clinic attenders

Measures of acceptability	Formula	Rate
<b>Referral rate</b>	$\frac{\text{Total referred to study}}{\text{All new gay male clinic attenders}^{(1)}}$	10.6% (499/4690)
<b>Response rate</b>	$\frac{\text{Agreed to participate}}{\text{Total referred to the study}}$	72.3% (361/499)
<b>Randomisation rate</b>	$\frac{\text{Total randomised}}{\text{Total referred \& eligible for randomisation}}$	71.3% (343/481)
<b>Attendance rate</b>	$\frac{\text{Completed intervention}}{\text{Total randomised to intervention}}$	70.9% (124/175)

<sup>(1)</sup> All new gay male clinic attenders = all men attending the GUM service reporting a male sexual partner, regardless of whether they met the study eligibility criteria.

Table 7 describes the referral rate rates by different clinic staff groups and the training and retention of intervention facilitators. These measures are useful indicators of the trial's acceptability among clinic staff. The distribution of doctor referrals is skewed (see Table 7) because the Table does not account for the fact that GUM services are largely junior doctor-led and most consultants work fewer clinical sessions each week in the men's GUM service.

As a consequence, the smaller numbers of referrals from some groups is not an indication of their lack of commitment to the trial.

**Table 7: Descriptive acceptability measures of the trial among clinical staff and intervention facilitators**

<b>Measures of acceptability</b>		<b>Number (%)</b>
<b>Total referred to the study</b>		<b>499 (100%)</b>
<b>Average monthly referral</b>		<b>19 (3.8%)</b>
<b>Average monthly recruitment</b>		<b>14 (4.1%)</b>
<b>Referrals by staff group</b>		
	Doctors	<b>168 (48.9%)</b>
	Consultants	11 (3.2%)
	Registrars	60 (17.4%)
	House officers/Clinical assistants	97 (28.3%)
	Nurses	<b>120 (35.0%)</b>
	Health Advisors	<b>24 (7.0%)</b>
	Trial Co-ordinator/self	<b>27 (7.9%)</b>
	Others/Not recorded <sup>(1)</sup>	<b>4 (1.2%)</b>
<b>Facilitators</b>		
	Eligible for training	<b>17</b>
	Completed training	<b>13</b>
	Remained involved throughout study	<b>6<sup>(2)</sup></b>

<sup>(1)</sup> Includes self-referral and referral from specialist clinics, for example the Mortimer Market Centre Specialist Dental Service.

<sup>(2)</sup> Three facilitators withdrew from the study and 4 left to take other jobs outside the clinic.

The training and retention of intervention facilitators shows a slightly different picture.

Facilitators were paid overtime rates for delivering the workshop and for attending the clinical supervision sessions. Of 17 staff that possessed appropriate experience and skills, 13 undertook the training and delivered at least one workshop. However, at the end of the trial only 6 of the original facilitators remained (1 woman and 5 men). It was primarily women facilitators that dropped out during the trial. It is not clear why they chose to end their involvement, but two women dropped out of the trial and all four of the facilitators who left the clinic to take jobs elsewhere during the study were women (see Table 7).

### *Feasibility*

During the main trial (January 1996–December 1997), there were 43 scheduled BIG Project Workshops and 33 ran (76.7%). Twelve workshops were cancelled – ten because the facilities were not available, for example during building work and the installation of new heating systems. Two were cancelled on the day: one because of insufficient numbers and one because of poor attendance due to bad weather. Workshops ran at approximately three-week intervals, although there was some variation to accommodate holiday periods and quiet periods at the clinic. Of 175 men allocated to the intervention group, 70.9% (124/75) completed the workshop. Overall 68% (84/124) of those allocated to the workshop attended on the date selected at enrolment. Men not attending on the date selected at enrolment had two further opportunities to attend before they were considered as ‘treatment failures’. There were no problems arranging facilitators to lead the workshops.

### *Summary*

Even after the changes instigated following the pilot phase, referral rates were lower than anticipated in the study protocol. But overall the response rate among men who spoke to a recruiter was higher than predicted in the original protocol (see Table 6). Staff participation in all aspects of the trial and ongoing commitment from many of the co-facilitators suggest that the trial was acceptable and well supported by both patients and clinic staff. The high attendance rates, clinical staff and facilitator commitment and the lack of logistical obstacles demonstrated that it was feasible to deliver the intervention within the context of a busy GUM clinic.

## **6.4 Quality assurance and fidelity of intervention delivery**

The final question set out in the introduction concerned the consistency of the intervention’s delivery. The importance of quality assurance and fidelity of intervention delivery, as distinct from process evaluation, has been highlighted in the behavioural intervention trials literature

(Kamb *et al.* 1996; Kelly *et al.* 2000a; O’Leary *et al.* 1997; National Institutes of Mental Health HIV Prevention Trial Study Group 1998; Spink Newmann & Sogolow 2000). Quality assurance and fidelity evaluation is important because investigators can only attribute trial outcomes to the effects of the intervention with certainty if they can be sure participants received the intervention, as intended by the researchers, regardless of who delivers it. In multi-site trials, of complex interventions without a fixed delivery formula – for example, one-to-one counselling – measuring quality and fidelity is often complicated and resource intensive (Kamb *et al.* 1996; O’Leary *et al.* 1997). Although the BIG Project Workshop was a multi-component complex intervention, steps were taken in the intervention and trial development stages to reduce potential for deviation from the prescribed delivery formula (see Figure 15). This made the quality assurance and fidelity assessment simpler, as it focused exclusively on consistency of delivery across different teams of co-facilitators, ensuring participants received the same intervention regardless of which workshop session they attended (O’Leary *et al.* 1997). Again, using a clinical trials analogy, the quality assurance and fidelity assessment in this trial aimed to make sure that the same ‘pill’ was delivered to all participants, regardless of who administered it. A combination of routine monitoring data, Participant Workshop Evaluation and Intervention Impact questionnaires, facilitators’ and clinical supervisors’ feedback reports and focus group discussions were all used to assess quality and fidelity of the intervention delivery.

### *Running time*

The expected running time of the workshops was seven hours, including breaks. Over the course of the 33 workshops, the average running time was approximately 6 hours 40 minutes. The shortest was 4 hours 55 minutes and the longest 7 hours 40 minutes. Running time did not appear to be influenced by the number of participants attending the workshop. In fact, some of the larger groups with 8 to 10 participants finished more quickly. Almost all exercises were completed within the time recommended by the investigators. However,

**Figure 15:** Steps taken in the design and development stages to promote quality and fidelity of delivery of the BIG Project Workshops

Quality assurance and fidelity measure	Description
Co-facilitator selection	<ul style="list-style-type: none"> <li>• Trained in HIV/STI prevention</li> <li>• Experience of working men's GUM services</li> <li>• Psychology or groupwork facilitation background</li> <li>• A counselling certificate and experience of group work</li> </ul>
Co-facilitator training	<ul style="list-style-type: none"> <li>• 2-day training programme in the delivery of BIG Project Workshop</li> <li>• 3-hour refresher session after 3 months</li> </ul>
Co-facilitator's delivery notes (see Appendix 4)	<ul style="list-style-type: none"> <li>• Comprehensive notes and guidance on delivery of each exercise of the workshop</li> </ul>
Facilitators' workshop materials	<ul style="list-style-type: none"> <li>• Pre-prepared flipcharts.</li> <li>• Participant worksheets</li> <li>• Other materials (e.g. condoms and demonstrators)</li> </ul>
Participant's workshop pack (provided in advance)	<ul style="list-style-type: none"> <li>• Outline briefing papers sent in advance by post</li> <li>• Introduced contents of BIG Project Workshop</li> <li>• Explained Workshop ground-rules</li> <li>• Provided names and details of co-facilitators</li> <li>• Described workshop logistics (e.g. dates, times, place &amp; directions)</li> </ul>
Participant's Workbook (see Appendix 3)	<ul style="list-style-type: none"> <li>• Comprehensive step-by-step description of each of the intervention's component exercises, including workspace for exercises</li> <li>• Simplified explanation of the cognitive-behavioural approach of the workshop, with references to original works</li> <li>• Other references, help-lines, etc.</li> </ul>

depending upon the dynamics of the group, some ran slightly longer, particularly ones involving whole group discussions. This appears to have been because in smaller groups men found it easier to engage in a group discussion and to ask more questions. The co-facilitators reported that none of the exercises consistently required either more or less time than originally allocated.

#### *Participant workshop evaluation questionnaires*

Only one participant failed to complete a Participant Workshop Evaluation questionnaire at the end of the day (99.2%; 123/124) (see Table 8). The purpose of this questionnaire was to get participant feedback about the workshop and to obtain participants' subjective assessment of the co-facilitators' performance.

The Participant Workshop Evaluation questionnaire results suggest that most were satisfied with the intervention, that it met both its stated aims and their expectations, and a high proportion found it useful. Nevertheless, some participants were less satisfied. The questionnaires were grouped according to the date of attendance to see whether any specific workshops stood out as being less successful, but there was no pattern and less satisfied participants seem to have been randomly distributed across all workshops. Overall the facilitators' performance was consistently highly rated by participants (see Table 8).

A relatively high proportion of men (57.7%; 77/123) indicated that they did not find any of the workshop exercises difficult or challenging. This was unanticipated and is difficult to interpret particularly given that nearly  $\frac{3}{4}$  of BIG Project Workshop attenders (73.8%; 90/123) indicated that given the opportunity they would attend the workshop again. One possible explanation for men's willingness to re-attend the workshops was that it somehow fulfilled a social function, as nearly half (45.5%; 55/121) also indicated that 'Meeting and

**Table 8: Results of Participant Workshop Evaluation questionnaires completed following the BIG Project Workshops (N = 123)**

	<b>Agree</b>	<b>Unsure</b>	<b>Disagree</b>
<b>Aims of workshop clearly explained</b>	<b>77.9%</b> (95/122)	<b>16.3%</b> (20/122)	<b>5.7%</b> (7/122)
<b>Aims and objectives met</b>	<b>69.7%</b> (85/121)	<b>28.9%</b> (35/122)	<b>1.6%</b> (2/122)
<b>Workshop met own expectations</b>	<b>62.3%</b> (76/123)	<b>30.9%</b> (38/123)	<b>7.3%</b> (9/121)
<b>Found workshop useful</b>	<b>80.2%</b> (97/121)	<b>16.5%</b> (20/121)	<b>3.3%</b> (4/121)
<b>Happy they attended</b>	<b>89.3%</b> (108/121)	<b>9.9%</b> (12/121)	<b>0.8%</b> (1/121)
<b>Found some sessions challenging</b>	<b>27.6%</b> (34/123)	<b>14.6%</b> (18/123)	<b>57.7%</b> (71/123)
<b>Given opportunity would attend again</b>	<b>73.8%</b> (90/122)	<b>22.1%</b> (27/122)	<b>4.1%</b> (5/122)
<b>Facilitators worked well together</b>	<b>92.3%</b> (112/121)	<b>6.6%</b> (8/121)	<b>0.8%</b> (1/121)
<b>Facilitators provided a safe environment</b>	<b>98.3%</b> (119/121)	<b>0.8%</b> (1/121)	<b>0.8%</b> (1/121)
<b><u>Most useful aspects of workshop</u></b>			
<b>Safer sex &amp; STI information</b>		<b>44.1%</b> (57/121)	
<b>Meeting and talking with other gay men</b>		<b>45.5%</b> (55/121)	
<b>Body Image exercise</b>		<b>28.1%</b> (34/121)	
<b>Lifestyle Balance exercise</b>		<b>24.8%</b> (30/121)	

talking with other gay men' was the most useful aspect of the workshop (see Table 8). This idea is explored in more detail in Chapter 8.

Each of the Workshop's component exercises was rated as being 'useful' by at least five participants, but three exercises were consistently described as the most useful (see Table 8). The most frequent criticisms of the workshop (15%; 12/80) were that participants felt it attempted to pathologise certain sexual behaviours and that there was an underlying assumption that all participants 'routinely' engaged in high-risk sexual behaviour. Some men, who did not have UAI, objected to this and to the facilitators being unwilling to discuss this issue in the group discussion sessions. However, because there is a large amount of missing data in response to this item (only 80/121 men entered anything) it would be ill advised to read too much into it.

### *Intervention Impact questionnaires*

The Intervention Impact questionnaire was completed at the same time as the Participant Workshop Evaluation questionnaire (i.e. at the end of the Workshop). Like the Workshop Evaluation questionnaire it was retained until the end of the trial and analysed in parallel with the main trial outcomes. The response rate was somewhat lower than the Participant Workshop Evaluation questionnaire at 84.9% (101/119). The questionnaire consisted of four attitudinal and psychometric scales taken from the baseline form: the Sexual Risk Cognition Questionnaire (SRCQ-22) (Shah *et al.* 1997); the Situational Self-Confidence Questionnaire (SSCQ) (Wanigaratne *et al.* 1997); the HIV Attitudes questionnaire (Hays *et al.* 1990) and the 'Readiness to Change' questionnaire (Rollnick *et al.* 1992). Table 9 presents descriptive results of the Intervention Impact questionnaire, comparing median scores for all intervention arm participants at baseline, and the changes in median 'within-individual' scores between baseline and post-intervention, for only those men who actually attended the Workshop. The results in Table 9 suggest there was a limited immediate intervention effect, but that this was



restricted to a small number of participants. For the Sexual Risk Cognition and Situational Self-Confidence questionnaires a lower score is suggestive of beneficial effect, while for the component scales of the HIV Attitudes questionnaire, a positive score increase reflects improvement. The range of the score changes indicates that the effect operated in both directions, but overall it was more likely to have been in a direction indicating benefit to the

**Table 9: Intervention Impact questionnaire: Median baseline scores on component scales for all randomised participants, Intervention participants only, and for intervention participants who completed questionnaire, ‘within-individual’ score changes between baseline and immediate post-intervention (N = 101)**

	<b><u>BASELINE</u></b> <b>All intervention participants</b> (n = 175)	<b><u>POST-INTERVENTION</u></b> <i>Change in within individual scores</i> (range) (n = 101)	<i>p-value<sup>(1)</sup></i>
<b>Sexual Risk Cognition (SCRQ-22):</b>	12	0	0.300
Median (range)	(0–72)	(-1.86– +1.59)	
<b>Situational Self-confidence (SCQ):</b>	8.0	0.27	0.0004
Median (range)	(0.8–10)	(-3.21– +3.60)	
<b>HIV Attitudes questionnaire</b> (Component scales):			
Median (range)			
Self-efficacy	4.5 (2.0 - 5.0)	0 (-2.0– +2.0)	0.63
Social norms	4.33 (2.33 - 5.0)	0 (-2.0– +2.7)	0.12
Communication skills	4.0 (1.0–5.0)	0 (-2.33– +2.0)	0.045
Self-labelling	3.33 (1.0–5.0)	0 (-2.67– +2.0)	0.0001
Safer sex efficacy	4.0 (1.5–5.0)	0 (-2.5– +3.0)	0.001
Interpersonal barriers	4.0 (2.0–5.0)	0 (-2.33– +2.0)	0.92
<b>‘Readiness to change’ (%)</b>			
Pre-contemplation	2.25 (1.0–4.0)	0 (-1.25– +1.0)	0.56
Contemplation	3.0 (1.0–5.0)	-0.25 (-2.25– +1.75)	0.001
Action	3.25 (2.0–5.0)	0 (-3.0– +2.0)	0.003

<sup>(1)</sup> Comparing within individual changes in scores between baseline and post-intervention, only for participants that attended the workshop and completed the Intervention Impact questionnaire (n = 101).

participant. To assess the quality assurance implications, participants' scores were grouped according to the date of the workshop, but there was no indication that more men who benefited from the intervention attended on specific days (data not shown). This provides some further evidence that the intervention was delivered consistently by all the facilitator teams.

#### *Facilitators and clinical supervisors' feedback*

Transcripts from the facilitator focus groups and the clinical supervisors' reports were examined in relation to facilitators' experience of the training provided and delivering the workshops to compare them with the results from the routine data, participant evaluations and Intervention Impact questionnaires.

The facilitators generally agreed that the workshop training was appropriate and adequate. Without exception, they felt that the first occasion running a workshop was the most difficult. However, the 'trouble-shooting' skills provided in the training gave them advance warning of likely difficulties and equipped them to handle most situations. Having an opportunity to meet in advance of a workshop to review the intervention content, decide who would lead on each exercise, and to re-examine their own personal trouble-shooting plans, helped each team of facilitators to feel comfortable, confident and properly supported by their co-workers.

There was general agreement that none of the workshop exercises presented significant delivery problems, although some of the women facilitators found that when doing pairs work, it was difficult for participants to relate to them and that they felt awkward working with men in this situation. This was especially so if the exercise dealt directly with sensitive or sexual issues. Facilitators generally felt more comfortable in workshops with more than 6 participants. In smaller groups, they felt there was greater potential for them to 'dominate' or 'swamp' the group, making it hard for participants to engage with each other. The first half

of the workshop was considered more difficult than the second. This was mainly because participants still had not had enough time to get to know each other and were still trying to assess their own feelings about being in the workshop. The morning exercises were also more theoretical and didactic which some participants found difficult. The 'High-risk situations' exercise (see Figure 6) was considered to be the most difficult exercise to deliver. This was confirmed in the clinical supervisors' report and the focus groups as the quote below suggests.

Sometimes people [participants] find it really hard to look at sex and risk situations, and identifying their own risk situations. Some of them will tell you all about things that really are risk situations, but they don't think of them as that. And a few have just looked at me a bit blank. I found it difficult to figure out whether they didn't want to be open about their risk situations, or whether they just didn't get it. I guess that's why I find that one hard.

(FG 1– M, p 6).

The focus groups and clinical supervisors' reports also confirmed that in every workshop all the exercises were covered. But covering all the exercises did not mean facilitators felt every workshop was a success. They tended to agree that the most successful groups were the ones where the participants bonded or gelled and in some way a group identity was formed. This was something that the facilitators could not engineer; rather, it seemed to happen spontaneously, often triggered by an unanticipated situation or event. Sometimes personal disclosure by a workshop member – for example, telling the group, directly or indirectly, their HIV status or admitting to feeling particularly vulnerable – was the kind of event that served as the catalyst that brought the group together.

'... during that exercise [Dealing with anxiety and stress] I was feeling it's really wordy and I'm talking too long ... I'm in the middle of it, and this guy's watch-alarm goes off. He excused himself. And then came back and explained that he had had to go and take his anti-viral medication [effectively disclosing that he was HIV+]. I thought I should feel anxious about this. But instead I thought that's what it needed. Now I know this group is going to work ...'

(FG 2 – M, p8).

'We had a similar thing with a guy with a caliper on his leg. When I first saw him my first thought was ... how's he going to cope with the Body Image, but that really turned out to be the moment when the group really came together.'

(FG 2 – F, p9).

### *Rating of exercises*

The facilitators agreed that in the early groups they felt most trepidation about the Body Image exercise, but with time it became one of their favourites. The Dealing with Anxiety and Stress exercise was also difficult because it was highly didactic, and hard to communicate the key cognitive-behavioural concepts in the limited time available. According to the clinical supervisors' report, all the facilitators, without exception, disliked the Safer Sex Experts exercise because, although it was intended to be participant-led, it always finished up being dominated by questions to the facilitators. Despite feeling less comfortable with this exercise, facilitators acknowledged it was the exercise participants consistently rated as most useful.

### *Summary*

The combination of data from different sources all seem to suggest that the intervention was delivered by different teams of facilitators with a high level of consistency and according to the structured programme developed by the investigators. Monitoring data confirm that the workshops were delivered within the time allocated. The Participant Workshop Evaluation and Intervention Impact questionnaires both suggest that a high proportion of men experienced the intervention in a similar way, but that for the majority there was a no immediate effect on motivation or confidence to change behaviour. Facilitator focus group discussions showed there was broad agreement about which exercises were the most difficult and that spontaneous events could cause the group to bond. With time, facilitators began to look out for these events because often they were key to making a workshop a success.

## **6.5 Conclusions**

The aim of this chapter was to answer four questions concerning the conduct, acceptability and targeting of the intervention, the integrity of the trial and the quality of the intervention delivery. Answering each of the questions has drawn on different process and quality

assurance data collected during the pilot phase and the main trial. The pilot phase demonstrated the need to modify the intervention, and both the referral and recruitment procedures, in order to optimise the research design, achieve the necessary sample size and obtain the required completion rate. The changes to the intervention format amounted to a significant deviation from the original delivery format. However, by retaining the core exercises and the CBT approach, the BIG Project Workshop remained true to its theoretical roots, was feasible to deliver and acceptable to trial participants, clinic staff and facilitators. Comparing the randomised men's socio-demographic, sexual behaviour and other HIV risk characteristics with those of non-responders, and other clinic attenders confirmed that simple eligibility criteria facilitated identification and recruitment of a sample at significantly increased risk of HIV, STI and other negative health outcomes. This could have important implications for the generalisability of the trial results. Finally, the data from the routine monitoring, Participant Workshop Evaluation and Intervention Impact questionnaires, focus groups and clinical supervisors' reports all combined to confirm that the intervention was delivered consistently to participants by different teams of facilitators over the entire intervention period. On the basis of these conclusions and the similarity between the trial arms in relation to their risk status at baseline, it is probably appropriate to attribute the outcome results discussed in the next chapter to the effects of the intervention.

## **Chapter 7**

### **Outcomes of the randomised controlled trial**

#### **7.0 Introduction**

This chapter describes the main results of the RCT. Like Chapter 5, it incorporates all the reporting criteria addressed in the revised CONSORT (Consolidated Standards of Reporting Trials) statement (Moher *et al.* 2001). It covers five key areas of the main outcome results. The first section explains the data management and statistical approaches. The second describes the characteristics of the study population and participant flow through each stage of the trial. The third and fourth sections report the primary and secondary outcomes based on the intention-to-treat analysis. The final section details the only planned sub-group analysis which involved an ‘on treatment’ analysis, where only those participants who completed the intervention were compared to controls for the main biological and behavioural outcomes.

The purpose of this sub-group analysis was to obtain an assessment of the overall efficacy of the intervention.

## **7.1 Data management and analysis**

All questionnaire and clinical record review data were double-entered using Epi-info (CDC & WHO 1997) and analysed using standard statistical software (SPSS Inc. 1996).

The primary analysis was based on all randomised participants (N = 343) regardless of whether or not they actually attended the intervention (intention-to-treat) (Moher *et al.* 2001; Pocock 1983). Non-randomised participants, that is, the regular male partners/boyfriends of randomised men enrolled in the study, were excluded from all the analyses presented.

The primary trial outcome was STI diagnosed at the clinic compared between the two trial arms at 12 month follow up. The main secondary outcomes were self-reported sexual behaviour change compared between the study arms. Other outcomes of interest included STI/HIV transmission knowledge, scores on a selection of attitudinal and psychometric scales and uptake of other HIV prevention services. These are presented along with the main indicators, the method and period of measurement and basis of the comparisons between the trial arms in Figure 16.

The main STI diagnosis outcome was based on cumulative proportions in each trial arm, from baseline to the end of the 12 month follow up, re-attending the clinic with a new STI diagnosed based on the clinic's reporting system (KC-60 reports) (PHLS, DHSS&PS, & Scottish ISD(D) Collaborative Group 2002). Other STI outcomes were based on self-reported diagnosis (questionnaires), the cross-sectional postal urine survey and matching to a regional database (Griffin *et al.* 1999). For sexual behaviour outcomes, comparisons were made of the proportions reporting the behaviour during the last-month at baseline, 6 and 12

**Figure 16:** Trial outcomes, main indicators and how they are presented in the main descriptive tables

<u>Outcome</u>	<u>Indicators</u>	<u>Measurement &amp; recall periods<sup>(1)</sup></u>	<u>Basis of comparisons between trial arms</u>
<i>Primary – STI diagnoses during follow up</i>			
	STI diagnoses at the clinic	Clinical & laboratory database review from baseline to 12 month follow up	Cumulative proportion with recorded STI diagnosis
	Self-reported STI diagnosis and treatment	Self-reports at 6 & 12 months	Cumulative proportion reporting an STI diagnosis
	Postal urine survey	End of trial only	Number of positive samples in each arm
	Matching to regional database	End of trial only	Numbers matched to clinic attendances and recorded STI diagnoses at other GUM clinics
<i>Secondary – Self-reported behaviours, knowledge and health status</i>			
High-risk sexual behaviours	UAI in last <i>month</i>	6 & 12 months	% reporting behaviour at each follow up
	UAI in last <i>year</i>	12 months only	% reporting behaviour at 12 months
	<i>All episodes of AI</i> condom protected in last <i>month</i>	6 & 12 months	% reporting behaviour at each follow up
	Number of sexual contacts in last <i>month</i>	6 & 12 months	Median and range at each follow up
	Number of sexual contacts in last <i>year</i>	12 months only	Median and range at 12 month follow up only
	Number of AI partners in last <i>month</i>	6 & 12 months	Median and range at each follow up
	Number of AI partners in last <i>year</i>	12 months only	Median and range at 12 month follow up only
	Number of UAI partners in last <i>month</i>	6 & 12 months	Median and range at each follow up
	Number of UAI partners in last <i>year</i>	12 months only	Median and range at 12 month follow up only
	Last episode <i>UAI with HIV discordant or unknown partner</i>	6 & 12 months	% reporting behaviour at each follow up
	Regular male partner	6 & 12 months	Cumulative % over 12 month follow up

<sup>(1)</sup> All secondary and self-reported measures were derived from the participant baseline questionnaire proforma.



**Figure 16 (cont'd):** Trial outcomes, main indicators and how they are presented in the main descriptive tables

<b>Outcome</b>	<b>Indicators</b>	<b>Measurement &amp; recall periods<sup>(1)</sup></b>	<b>Basis of comparisons between trial arms</b>
<i>Secondary - Self-reported behaviours, knowledge and health status (cont'd)</i>			
Health Behaviour	HIV test in last year	6 & 12 months	Cumulative % over 12 month follow up
	Recreational drug use in last year	6 & 12 months	Cumulative % over 12 month follow up
STI/HIV transmission risk knowledge	STI/HIV Knowledge scale	6 & 12 months	Comparison of mean scores at each follow up
<i>Other secondary – Attitudinal and psychometric scales and uptake of HIV prevention</i>			
Intervention effect	Attitudinal and psycho-metric measures	6 & 12 months	Comparison of median scores at each follow up
	'Readiness to Change' questionnaire	6 & 12 months	% assigned to different stages of model at each follow up
Uptake of prevention services	Range of clinic and community-based HIV prevention services	6 & 12 months	Cumulative % over 12 month follow up

<sup>(1)</sup> All secondary and self-reported measures were derived from the participant baseline questionnaire proforma. made of the proportions reporting the behaviour during the last-month at baseline, 6 and 12 month follow ups, or during the last year at baseline and 12 month follow up. For other outcomes, for example HIV testing and recreational drug use, comparisons were made of the cumulative proportions reporting the behaviour during the last year at baseline, 6 and/or 12 months. For STI/HIV knowledge and psycho-social measures, data were compared between the trial arms at baseline, 6 and 12 month follow up using median and mean scores on the respective measures.

month follow ups, or during the last year at baseline and 12 month follow up. For other outcomes, for example HIV testing and recreational drug use, comparisons were made of the cumulative proportions reporting the behaviour during the last year at baseline, 6 and/or 12 months. For STI/HIV knowledge and psycho-social measures, data were compared between the trial arms at baseline, 6 and 12 month follow up using median and mean scores on the respective measures.

Preliminary analysis of the main behavioural outcomes suggested there was a positive change in both trial arms in respect to some measures. To see whether it was the same men who reported the behaviours at baseline and each follow up or whether there was in fact a genuine positive shift involving a larger group of different men, selected behavioural measures were compared for 'within-arm' changes from baseline to 12 month follow up. The same approach was adopted in analysing the attitudinal and psychometric scale scores. These results provide a better indication of whether the intervention achieved its objective at a cognitive level of moving participants towards more behaviour change.

Basic statistical techniques for randomised clinical controlled trials were used in the main analysis. This included chi-squared ( $\chi^2$ ) tests for binary data and Mann-Whitney tests for continuous data, for unadjusted comparisons between arms; Wilcoxon signed rank test and McNemar's chi-squared ( $\chi^2$ ) test for matched observations for 'within-arm' and 'within-individual' changes; and crude and adjusted odds ratios with 95% confidence intervals (95% CI) for the main STI and selected behavioural outcome measures. Statistical significance is considered as  $p = 0.05$  for all analyses. Adjustment for possible baseline confounding factors was achieved through logistic regression. The main factor requiring adjustment was

presentation with an acute STI at baseline, as this was already known to confer greater risk of re-attendance with a new STI within 12 months (unpublished clinic data).

The only planned sub-group analysis was an 'on treatment' analysis (comparing those who attended the intervention with the controls). Further analysis, to show whether the effect of the intervention differed according to age or eligibility (having an STI at recruitment) through testing for an interaction between these factors and the trial arm have been incorporated and are presented in the main analysis. Exploratory analyses to test specific hypotheses that help explain the trial results are described in the next chapter.

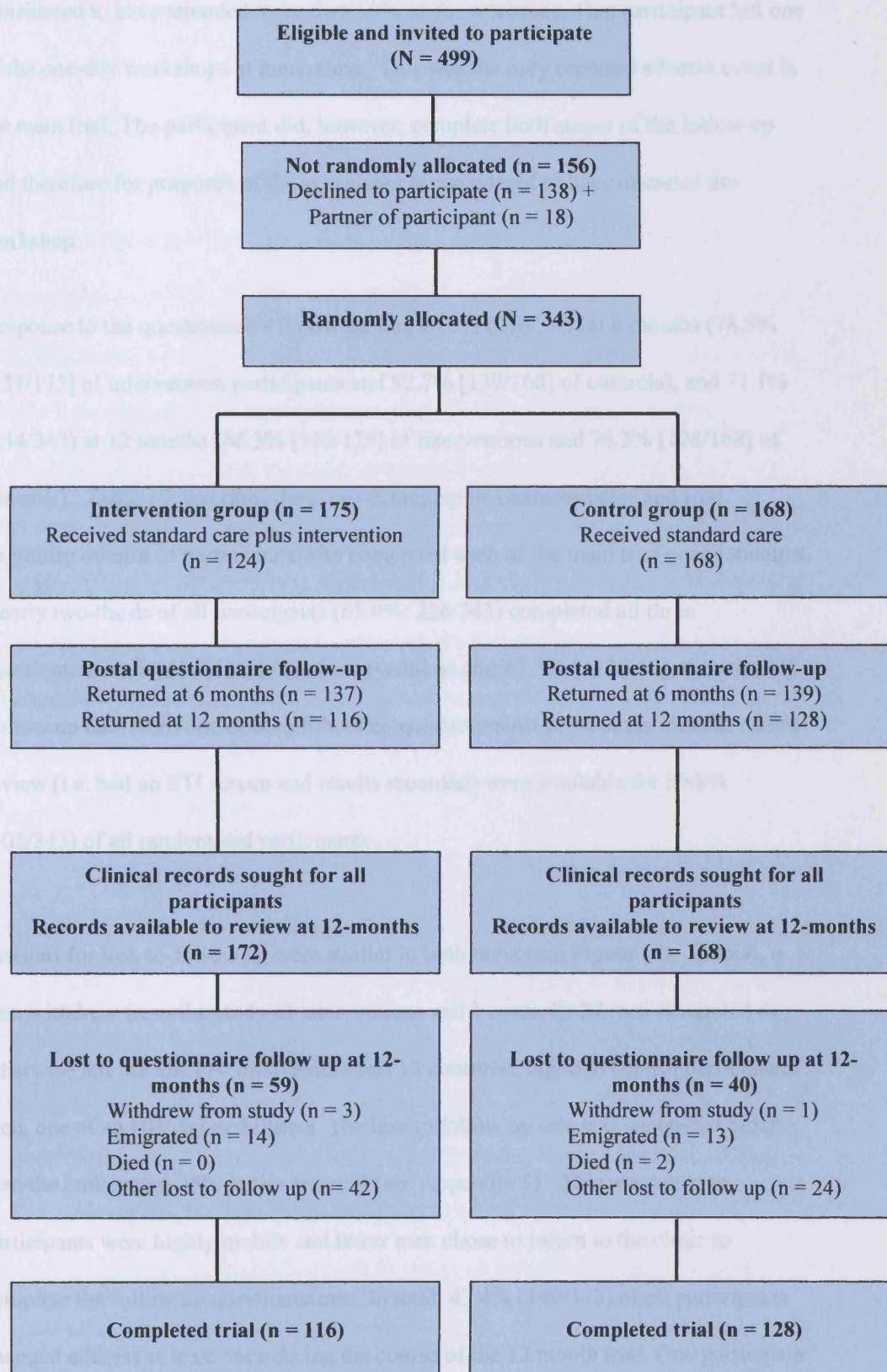
## **7.2 Trial flow and follow up**

Figure 17 illustrates the movement of participants through each stage of the trial.

From October 1995 to November 1997, 499 eligible men were invited to participate in the study. In total, 156 men either declined to participate (27.7%; 138/499) or were not randomised for other reasons (3.6%; 18/499) (regular male partners/boyfriends of randomised men) (see Section 5.9). This gave an overall response rate, that is men who agreed to join the study, of 72.3% (361/499). After exclusion of non-randomised participants ( $n = 18$ ), a total of 343 of the original 499 (68.7%) were retained in the main outcome analyses. At this point there were 175/343 (51.0%) randomised men assigned to the intervention and 168/343 (49.0%) assigned to the control condition. There were no significant deviations from the protocol in respect to the inclusion or exclusion of participants from the analysis.

Of the 175 men allocated to the intervention, 70.9% (124/175) completed the full intervention ( $n = 114$ ) or attended more than 50% ( $n = 10$ ). Among men involved in

**Figure 17: Participants' progress through the trial**



the pilot sessions (see Figure 13), those who attended at least two sessions of the three-session format ( $n = 4$ ) or one session of the two session format ( $n = 5$ ) were considered to have attended more than 50% of the workshop. One participant left one of the one-day workshops at lunch time. This was the only reported adverse event in the main trial. The participant did, however, complete both stages of the follow up and therefore for purposes of these analyses is considered to have attended the workshop.

Response to the questionnaire follow up was 80.5% (276/343) at 6 months (78.3% [137/175] of intervention participants and 82.7% [139/168] of controls), and 71.1% (244/343) at 12 months (66.3% [116/175] of interventions and 76.2% [128/168] of controls). Table 10 describes the socio-demographic characteristics and trial eligibility criteria of participants who completed each of the main trial questionnaires. Nearly two-thirds of all participants (65.9%; 226/343) completed all three questionnaires (64.6% [113/175] of interventions and 67.3% [113/168] of controls)]. Follow up data from one or both follow up questionnaires or from the clinical record review (i.e. had an STI screen and results recorded) were available for 89.8% (308/343) of all randomised participants.

Reasons for loss-to-follow up were similar in both arms (see Figure 17). In total, 4 men withdrew from the study (3 interventions and 1 control); 27 men emigrated or otherwise left the UK (14 intervention and 13 controls); and two control participants died, one of an HIV-related illness. The loss to follow up rate was somewhat higher than the anticipated 25% in the protocol (see Appendix 5). This was because participants were highly mobile and fewer men chose to return to the clinic to complete the follow up questionnaires. In total, 43.4% (149/343) of all participants changed address at least once during the course of the 12 month trial. One participant

informed the study of 7 changes of address over the course of his involvement in the trial. No information was available on the remaining 66 men lost-to-follow up; however, what seems most likely, is that they moved home without notifying the study team.

### **7.3 Baseline results**

At baseline, both trial arms were similar in respect to the key socio-demographic characteristics, with the possible exception of occupational classification (see Table 10). Men classified as 'professional' or 'skilled non-manual' were more likely to be allocated as controls ( $p = 0.056$ ) (Office of Population and Censuses and Surveys 1991). None of the socio-demographic or eligibility criteria were significant predictors of whether or not men completed follow up questionnaires, with the exception of age. Older men were significantly more likely to complete the 6 month follow up ( $p = 0.019$ ) and 12 month follow up questionnaires ( $p < 0.001$ ). The median age (at baseline) of those participants that returned the 6 month follow up was 29 years and 29.5 years for the 12 month follow up, compared to a median age of 27 years at baseline for those who did not.

Both groups were broadly similar at each stage of follow up with the exception of age, and a borderline significant difference in respect to occupation classification ( $p = 0.066$ ) at 12 month follow up (see Table 10). At 6 month follow up intervention, men who returned the questionnaire were significantly older than the comparable group of controls ( $p = 0.048$ ). This trend continued at 12 month follow up, although at this stage it was not statistically significant ( $p = 0.175$ ). The borderline significant difference in occupational classification at 12 month follow up reflects the same baseline observation.

**Table 10:** Baseline characteristics of the cohort, by study arm and follow up completion

	<b><u>All Participants at Baseline</u></b>				<b><u>Completed 6 month follow up</u></b>					<b><u>Completed 12 month follow up</u></b>				
	<b>All (N = 343)</b>	<b>Intervention (n = 175)</b>	<b>Control (n = 168)</b>	<b>p- value<sup>(1)</sup></b>	<b>All (N = 276)</b>	<b>Intervention (n = 137)</b>	<b>Control (n = 139)</b>	<b>p- value<sup>(1)</sup></b>	<b>p- value<sup>(2)</sup></b>	<b>All (N = 244)</b>	<b>Intervention (n = 116)</b>	<b>Control (n = 128)</b>	<b>p- value<sup>(1)</sup></b>	<b>p- value<sup>(2)</sup></b>
<b>Identification:</b>														
Gay	<b>93.9%</b> (321/342)	93.7% (163/174)	94.0% (158/168)	1.00	<b>93.8%</b> (258/275)	92.06% (126/136)	95.0% (132/139)	0.462	1.00	<b>93.8%</b> (228/243)	91.3% (105/115)	96.1% (123/128)	0.181	0.969
<b>Age:</b>														
Median (range)	<b>29</b> (18 - 58)	29 (18 - 49)	29 (18 - 58)	0.378	<b>29</b> (18 - 51)	31 (18 - 49)	29 (18 - 51)	0.048	0.019	<b>29.5</b> (18 - 51)	32 (19 - 49)	29.5 (18 - 51)	0.175	<0.001
<b>Ethnicity:</b>														
White	<b>90.6%</b> (310/342)	91.4% (159/174)	89.9% (151/168)	0.386	<b>90.5%</b> (249/275)	90.4% (123/136)	90.6% (126/139)	1.00	0.899	<b>92.2%</b> (224/243)	91.3% (105/115)	93.0% (119/128)	0.642	0.127
<b>Education:</b>														
Beyond secondary School	<b>85.7%</b> (293/342)	85.6% (149/174)	85.7 (144/168)	1.00	<b>86.9%</b> (239/275)	89.7% (122/136)	84.2% (117/139)	0.211	0.187	<b>87.2%</b> (212/243)	88.7% (102/115)	85.9% (110/128)	0.567	0.195
<b>Occupation:</b>														
Professional/ Skilled non-manual <sup>3</sup>	<b>56.8%</b> (193/340)	52.3% (91/174)	61.4% (102/166)	0.056	<b>57.7%</b> (158/274)	53.7% (73/136)	61.6% (85/138)	0.221	0.496	<b>59.5%</b> (144/242)	53.0% (61/ 15)	65.4% (83/127)	0.066	0.110
<b>Eligibility criteria:</b>														
Acute STI	<b>49.9%</b> (168/337)	52.6% (90/171)	47.0% (78/166)	0.177	<b>48.0%</b> (130/271)	48.9% (65/133)	47.1% (65/138)	0.808	0.607	<b>49.0%</b> (117/239)	49.1% (55/112)	48.8% (62/127)	1.00	0.607

<sup>(1)</sup> Comparing intervention and control arms at each stage of the trial.

<sup>(2)</sup> Comparing All participants at baseline, and All participants at 6 month follow up, and All participants at baseline and All participants at 12 month follow up.

<sup>(3)</sup> Social classes I, II, III (Office of Population and Censuses and Surveys 1991).

#### **7.4 Primary trial outcome – ‘New STI diagnoses’**

The primary trial endpoint was the cumulative proportion in each arm with a ‘new STI diagnosed’ at the clinic during the 12 month follow up. To increase the accuracy of this measure two definitions of new STI diagnosis were used. The aim of having two definitions was to distinguish between all STI diagnoses in the follow up and those that could, with some certainty, be attributed to acquisition during the follow up period. The first definition included all clinical or laboratory diagnosed STI recorded on the clinic's databases over the 12 month follow up. The first definition was broadly conceived and included acute hepatitis B infection, first clinical episode of genital herpes and warts, syphilis, gonorrhoea and chlamydia. However, because some viral infections can be latent for some time before becoming symptomatic leading to an acute presentation, it is possible that some of the new STI diagnoses according to this definition were, in fact, infections acquired outside the time frame of the trial and only resulted in presentation at the clinic during follow up. These would almost certainly be viral infections, herpes and genital warts specifically, and possibly early latent or late latent syphilis. The second definition of new STI was a narrow definition limited to new bacterial STI diagnoses only (primary and secondary syphilis, chlamydia, gonorrhoea) that, because of the more rapid onset of symptoms, provide a better indicator of recent high-risk sexual practice. Primary and secondary syphilis infections based on clinical symptoms were included in this definition; however, no cases were identified in the sample.

Four information sources illustrated in Figure 18 provided the data on new STI diagnoses among participants. Only data from the objective data sources were incorporated into this analysis, because there was substantial discrepancy between participants’ self-reports of STI treatment and the results of the clinic record review. The results of the postal urine survey and the matching to the regional database were used to confirm the clinic record review results, not to identify further trial endpoints (additional STI diagnoses). Participant self-reports are presented for completeness of reporting only.



**Figure 18:** Source, identification procedure and total number of sexually transmitted infections identified among all randomised participants

<b><u>Data Source (base)</u></b>	<b><u>Identification Procedure</u></b>	<b><u>Total STI</u></b>	
		<b><u>Intervention</u></b>	<b><u>Control</u></b>
Clinic record review (N = 340)	Review of <i>all</i> randomised participants for screening and STI diagnoses at the Clinic through the 12 months of follow up	172 records reviewed 188 STI screens in 91 participants <b>82 STI diagnoses</b>	168 records reviewed 163 STI screens in 81 participants <b>56 STI diagnoses</b>
Self-reports (N = 244)	Follow up questionnaire items on STI diagnoses	35 diagnoses reported <hr/> 116 questionnaires returned	42 diagnoses reported <hr/> 128 questionnaires returned
Matching to regional database (N = 191)	STI diagnoses identified in a regional database of attendances at other clinics in Greater London	4 attendances 0 diagnoses recorded <hr/> 98 successful matches	4 attendances 1 diagnosis recorded <hr/> 93 successful matches
Anonymous postal urine survey (N = 262)	STI diagnoses <sup>(1)</sup> among those able to participate in anonymous postal urine survey	1 diagnosis <hr/> 122 invited to participate	4 diagnoses <hr/> 140 invited to participate

<sup>(1)</sup> Urethral gonorrhoea, chlamydia, and HIV.

In total, 144 STI diagnoses were attributed to study participants over the course of the trial and 143 of these were diagnoses made in the clinic's laboratories. One diagnosis identified from the regional database was attributed to another clinic (see Figure 18). According to the record review data, the distribution of new STI diagnoses was generally similar in each phase of the follow up (47.1% [65/138] of diagnoses occurring between baseline and 6 months, and 52.9% [73/138] between 6 and 12 months).

### *Record review results*

Table 11 presents results of the new STI diagnosed at the clinic using the two different definitions. About half of all participants (50.6%; 172/340) (52.9% [91/172] intervention and 48.2% [81/168] controls) reattended the clinic at least once for an STI screen during the follow up. A higher proportion of men in the intervention group had a new STI diagnosed at the clinic by either definition (see Table 11). This was not appreciably affected by adjusting for baseline differences in presentation with an acute STI. Restricting the analysis to only those men only who reattended the clinic and had an STI screen had little effect on the likelihood of having an STI diagnosed (Adjusted odds ratios 1.841 [95% CI 0.996 – 3.40] for the broad definition and 1.844 [95% CI 0.823 - 4.164] for the narrow definition). This was because although more intervention than control participants reattended and had an STI screen, the proportion of intervention men whose screens resulted in an STI diagnosis was higher than in the control group by either definition (58.2% [53/91] vs. 43.2% [35/81] for the broad definition, and 23.1% [21/91] vs. 13.6% [11/81] for the narrow definition).

Record review data were also analysed by site of infection – presuming rectal infections to be a better indicator recent high-risk sexual practice (Singaratnam *et al.* 1991; Young *et al.* 1991). The absolute numbers of diagnoses of rectal infections was small (n = 13) and involved gonorrhoea only. Clinic protocol at the time required collection of rectal specimens for

**Table 11:** New STI diagnosed at the clinic during 12 months of follow up based on record review, with crude and adjusted odds ratios

<b>All men (N = 340)</b>	<b>Intervention (n = 172)</b>	<b>Control (n = 168)</b>	<b>Odds Ratio (95% CI)</b>	<b>Adjusted Odds Ratio<sup>(1)</sup> (95% CI)</b>
<b>Any new STI diagnosed <sup>(2)</sup></b>	30.8% (53/172)	20.8% (35/168)	1.692 (1.033–2.772)	1.659 (1.004–2.743)
<b>New bacterial STI diagnosed <sup>(3)</sup></b>	12.2% (21/172)	6.5% (11/168)	1.984 (0.925–4.255)	1.844 (0.851–3.993)
<b>Men requesting a screen (N = 172)</b>	<b>Intervention (n = 91)</b>	<b>Control (n = 81)</b>		
<b>Any new STI diagnosed <sup>(2)</sup></b>	58.2% (53/91)	43.2% (35/81)	1.833 (1.000–3.359)	1.838 (0.993–3.340)
<b>New bacterial STI diagnosed <sup>(3)</sup></b>	23.1% (21/91)	13.6% (11/81)	1.909 (0.857–4.254)	1.843 (0.817–4.159)

<sup>(1)</sup> STI odds ratios adjusted for eligibility at baseline (presenting with an acute STI).

<sup>(2)</sup> A broad definition of new STI includes hepatitis B, first episodes of herpes and warts, early-latent syphilis, gonorrhoea, chlamydia and non-specific urethritis.

<sup>(3)</sup> A narrow definition of new STI includes only bacterial STI diagnosed at the clinic that included primary and secondary syphilis, chlamydia and gonorrhoea.

gonorrhoea only. However, the incidence of rectal gonorrhoea diagnoses was non-significantly higher ( $p = 0.26$ ) in the intervention group ( $n = 9$ ) than in the controls ( $n = 4$ ).

This higher rate of new STI diagnoses in the intervention group was unexpected and, as shown in the subsequent sections, ran counter to the self-reported STI, sexual behaviour and personal HIV risk reduction measures. Because of this, the record review of clinic and laboratory diagnoses was extended for all participants beyond the 12 months to see if this apparent adverse effect persisted. At completion of this extended clinical record review, the median follow up period for all participants was 22 months (range 18–36 months). The results are presented in Table 12. In an intention-to-treat analysis, the extended record review results produced an odds ratio which, when adjusted for eligibility at baseline (i.e. presenting with an acute STI) was 0.963 (95% CI 0.560–1.650) compared to 1.69 (95% CI 1.004–2.743) at 12 months for the broad definition. For the narrow definition, the extended follow up adjusted odds ratio was 1.304 (95% CI 0.533–3.192) compared to 1.602 (95% CI 0.533–4.814) at 12 months. The reduced adjusted odds ratios in the extended follow up offered some reassurance that the difference between the arms in the likelihood of having a new STI attenuated over time.

### *Self-reported STI*

Similar proportions of intervention and control participants reported ever having had an STI at baseline (see Table 12) (57.5% [100/174] of intervention men and 54.2% [91/168] of controls [ $p = 0.586$ ]). The proportions reporting an STI diagnosis during follow up were similar, although slightly higher for controls than for interventions at each stage (6 month 26.3% [36/137] interventions vs. 27.3% [38/139] controls ( $p = 0.892$ ); and 12 month 30.2% [35/116] interventions vs. 32.85 [42/128] controls ( $p = 0.681$ )). Interestingly, these results were largely consistent with the data obtained from the clinical record review for intervention

**Table 12:** STI diagnosed at the clinic beyond 12 months based on extended record review, with crude and adjusted odds ratios

	<b>Intervention</b> (n = 172)	<b>Control</b> (n = 168)	<b>Odds Ratio</b> (95% CI)	<b>Adjusted Odds Ratio<sup>(1)</sup></b> (95% CI)
<b>Any new STI diagnosed <sup>(2)</sup></b>	20.9% (36/172)	20.2% (34/168)	1.043 (0.617–1.765)	0.963 (0.560–1.650)
<b>New bacterial STI diagnosed <sup>(3)</sup></b>	7.0% (12/172)	5.4% (9/168)	1.325 (0.543–3.232)	1.304 (0.533–3.192)

<sup>(1)</sup> STI odds ratio adjusted for eligibility at baseline (presenting with an STI).

<sup>(2)</sup> A broad definition of new STI includes hepatitis B, first episodes of herpes and warts, early-latent syphilis, gonorrhoea, chlamydia and non-specific urethritis.

<sup>(3)</sup> A narrow definition of new STI includes only bacterial STI diagnosed at the clinic included primary and secondary syphilis, chlamydia and gonorrhoea.

**Table 13:** Self-reported STI diagnoses at baseline, 6 and 12 month follow up among all participants

	<b><u>Baseline</u></b> (N = 343)			<b><u>6 Month</u></b> (N = 276)			<b><u>12 Month</u></b> (N = 244)		
	<u>Intervention</u> (n = 175)	<u>Control</u> (n = 168)	<i>p-value<sup>(1)</sup></i>	<u>Intervention</u> (n = 137)	<u>Control</u> (n = 139)	<i>p-value<sup>(1)</sup></i>	<u>Intervention</u> (n = 116)	<u>Control</u> (n = 128)	<i>p-value<sup>(1)</sup></i>
Ever had an STI diagnosed/ STI diagnosis during follow up	57.5% (100/174)	54.2% (91/168)	0.586	26.3% (36/137)	27.3% (38/139)	0.892	30.2% (35/116)	32.8% (42/128)	0.681

<sup>(1)</sup> Comparing Intervention and Control at each stage of the trial.

participants but much higher for the controls, which reaffirms the importance of objectively measured clinical endpoints.

#### *Regional database matching*

As a check that the observed difference in the rate of new STI diagnoses was not the product of any systematic ascertainment bias – for example that some men, particularly controls, opted to attend at other clinics for STI screens, participants' data were matched to a person-based anonymised database of attendances and STI diagnoses at 23 London GUM clinics (Griffin *et al.* 1999). Four criteria needed to achieve a close match between BIG Project participants and the database. These were sex, age, likely route of acquisition (homosexually or heterosexually acquired) and the first four items of the residential postcode. At the time matching was undertaken, the necessary data were available for 55.6% (191/343) of participants (98 intervention and 93 controls) (see Figure 18). Four men in each arm (4.1% [4/98] of interventions and 4.3% [4/93] of controls) could be matched to an attendance at another London GUM clinic. Only one attendance, involving a control participant, resulted in a reported diagnosis. This offered important re-assurance that the record review results were not affected by any systematic bias because of attendance at other London GUM clinics.

#### *Postal urine survey*

As a further check for potential bias in the record review data, in this case that rates of prevalent undiagnosed STI were different between the two groups, an anonymous cross-sectional postal urine survey of all participants was undertaken at the end of the trial. The survey involved 79.1% (262/343) of originally randomised men for whom postal contact details were available (69.7% [122/175] of interventions and 83.3% [140/168] of controls). At the time of the survey, the median time since randomisation was 22 months (range 15–36 months). Urine specimens were returned by 68.7% (180/262) of the participants approached, or 52.5% (180/343) of the original cohort. Of the returned specimens only 1 tested positive

for gonorrhoea (control) and 4 for chlamydia (1 intervention, 3 controls) (see Figure 18). The urine specimens were also tested separately for HIV; however, no infections were detected that had not already been either self-reported or identified by clinic record review. These results provided further reassurance that there had not been any systematic bias in the identification of new STI diagnoses in the clinic record review.

## 7.5 Main secondary trial outcomes – Sexual behaviour changes

Table 14 presents the full results of the intention-to-treat analysis for the main and the other secondary trial outcomes based on participants' self-reports from the baseline and follow up questionnaires. Over time, neither group reported large or wholly consistent changes in a direction that would suggest a strong intervention effect either way. However, comparing between the arms, there was generally more improvement among the intervention than among the control participants.

### *Sexual behaviour, sexual partnerships and HIV risk reduction*

The largest improvement in sexual behaviour and HIV risk reduction was in the proportion of the intervention group reporting any UAI in the last month. This dropped from 36.6% (63/172) at baseline to 23.5% (32/136) at 6 month follow up and 27.2% (31/114) at 12 months. By comparison, proportions in the control group changed very little (30.1% [50/166] at baseline to 31.7% [44/149] at 6 month follow up and 31.5% [39/124] at 12 month follow up) (see Table 14, p. 162). Comparing between the trial arms at each stage, and after adjusting for baseline eligibility criteria (recruited with an STI and self-reported UAI in last 12 months), the differences did not achieve statistical significance ( $p = 0.07$  at 6 month and  $p = 0.31$  at 12 months). Analysing only those men who reported AI in the last month at baseline and each follow up, over the course of the trial there was an increase in the proportion of intervention participants who reported all episodes of AI were condom protected (48.8% [60/123] at baseline to 63.4% [59/93] at 6 month and 63.3% [50/79] at 12

**Table 14:** Results of the main and other secondary trial outcomes based on participant self-reports at baseline, 6 and 12 month follow up

	<b><u>Baseline</u></b>			<b><u>6 Month</u></b>			<b><u>12 Month</u></b>		
	<u>Intervention</u> (n = 175)	<u>Control</u> (n = 168)	<i>p-value<sup>(1)</sup></i>	<u>Intervention</u> (n = 137)	<u>Control</u> (n = 139)	<i>p-value<sup>(1)</sup></i>	<u>Intervention</u> (n = 116)	<u>Control</u> (n = 128)	<i>p-value<sup>(1)</sup></i>
<b><u>Main Secondary Outcomes</u></b>									
<b><u>Sexual behaviour and sexual partnerships:</u></b>									
% reporting any UAI in last month	36.6% (63/172)	30.1% (50/166)	0.249	23.5% (32/136)	31.7% (44/139)	0.140	27.2% (31/114)	31.5% (39/124)	0.481
% reporting any UAI in last year	60.9% (106/174)	62.7% (104/166)	0.823	-----	-----	---	50.0% (58/116)	59.4% (76/128)	0.158
% reporting all episodes of AI in last month condom protected <sup>(2)</sup>	48.8% (60/123)	61.4% (78/127)	0.045	63.4% (59/93)	54.5% (55/101)	0.243	63.3% (50/79)	60.0% (57/95)	0.755
Number of sexual contacts in last month – Median (range)	3 (0–60)	3 (0–45)	0.801	3 (0–20)	3 (0–40)	0.382	2.5 (0–25)	2 (0–40)	0.869
Number of sexual contacts in last year – Median (range)	20 (1–300)	20 (0–500)	0.648	-----	-----	---	23 (1–299)	20 (1–390)	0.920
Number of AI partners in last month – Median (range)	1 (0–12)	1 (0–30)	0.540	1 (0–15)	1 (0–25)	0.038	1 (0–7)	1 (0–20)	0.195
Number of AI partners in last year – Median (range).	3 (0–100)	4 (0–300)	0.198	-----	-----	---	6 (0–60)	5 (0–190)	0.800

<sup>(1)</sup> Comparing intervention and control at each stage of the trial.

<sup>(2)</sup> Base is those who reported 1 or more episodes of anal intercourse in the last month.



**Table 14 (cont'd): Results of the main and other secondary trial outcomes based on participant self-reports at baseline, 6 and 12 month follow up**

	<b><u>Baseline</u></b> (N = 343)			<b><u>6 Month</u></b> (N = 276)			<b><u>12 Month</u></b> (N = 244)		
	<u>Intervention</u> (n = 175)	<u>Control</u> (n = 168)	<i>p-value<sup>(1)</sup></i>	<u>Intervention</u> (n = 137)	<u>Control</u> (n = 139)	<i>p-value<sup>(1)</sup></i>	<u>Intervention</u> (n = 116)	<u>Control</u> (n = 128)	<i>p-value<sup>(1)</sup></i>
<b><u>Sexual behaviour and sexual partnerships:</u></b> (cont'd)									
Total UAI partners in last <i>month</i> – Median (range)	0 (0–4)	0 (0–3)	0.183	0 (0–3)	0 (0–6)	0.210	0 (0–4)	0 (0–3)	0.841
Total UAI partners in last <i>year</i> – Median (range)	1 (0–60)	1 (0–40)	0.812	-----	-----	---	1 (0–47)	1 (0–21)	0.306
% reporting that last episode of UAI with partner of unknown or different HIV status <sup>2</sup>	62.9% (39/62)	68.0% (34/50)	0.690	43.8% (14/32)	65.1% (28/43)	0.099	48.4% (15/31)	46.2% (18/39)	1.00
% reporting currently having a regular male partner (RMP) or boyfriend	48.5% (83/171)	48.8% (81/166)	0.962	53.9% (69/128)	53.1% (68/128)	0.530	51.3% (58/113)	55.3% (68/123)	0.602
Current RMP/boyfriend same as baseline	-----	-----		70.0% (49/70)	59.1% (39/66)	0.211	63.8% (37/58)	50.0% (34/68)	0.150
<b><u>Health status:</u></b>									
% reporting having had an HIV test in the last <i>year</i> .	61.7% (108/175)	61.7% (103/167)	1.000	-----	-----	---	56.5% (65/115)	54.7% (70/128)	0.797
% reporting HIV status as 'HIV positive'	1.1% (2/175)	1.8% (3/167)		-----	-----	---	5.9% (4/68)	10.1% (7/69)	0.532

<sup>(1)</sup> Comparing intervention and control at each stage of the trial.

<sup>(2)</sup> Base is those who reported any UAI in the last month.

**Table 14:** (cont'd) Results of the main and other secondary trial outcomes based on participant self-reports at baseline, 6 and 12 month follow up

	<b>Baseline</b> (N = 343)			<b>6 Month</b> (N = 276)			<b>12 Month</b> (N = 244)		
	<u>Intervention</u> (n = 175)	<u>Control</u> (n = 168)	p-value <sup>(1)</sup>	<u>Intervention</u> (n = 137)	<u>Control</u> (n = 139)	p-value <sup>(1)</sup>	<u>Intervention</u> (n = 116)	<u>Control</u> (n = 128)	p-value <sup>(1)</sup>
<b><u>STI/HIV knowledge:</u></b>									
% of items answered correctly	61.2%	62.7%	0.429	65.9%	63.5%	0.139	65.4%	62.4%	0.642
Mean (standard deviation)	(SD 0.161)	(SD 0.156)		(SD 0.131)	(SD 0.135)		(SD 0.144)	(SD 0.139)	
<b><u>Uptake of prevention services:</u></b>									
Had one-to-one counselling (community)	----	----	---	----	----	---	11.4% (13/114)	4.7% (6/127)	0.060
Had one-to-one counselling (clinic)	----	----	---	----	----	---	15.8% (18/114)	17.5% (22/126)	0.863
Attended 'Getting the sex you want'.	----	----	---	----	----	---	12.6% (14/111)	5.5% (7/127)	0.067
Contacted a helpline	----	----	---	----	----	---	15.8% (18/114)	16.7% (21/126)	0.863
<b><u>Drug use:</u></b>									
% reporting use of a Class A drug in last year. (e.g. heroin, cocaine, crack)	36.6% (63/172)	36.5% (61/167)	1.00	----	----	---	24.5% (27/110)	31.7% (38/120)	0.244
% reporting use of 'club' drugs in last year (e.g. ecstasy, acid, poppers)	55.2% (95/172)	57.8% (96/166)	0.630	----	----	---	81.9% (95/116)	86.4% (108/125)	0.379

<sup>(1)</sup> Comparing intervention and control at each stage of the trial.

**Table 14:** (cont'd) Results of the main and other secondary trial outcomes based on participant self-reports at baseline, 6 and 12 month follow up

	<b><u>Baseline</u></b> (N = 343)			<b><u>6 Month</u></b> (N = 276)			<b><u>12 Month</u></b> (N = 244)		
	<u>Intervention</u> (n = 175)	<u>Control</u> (n = 168)	<i>p-value</i> <sup>(1)</sup>	<u>Intervention</u> (n = 137)	<u>Control</u> (n = 139)	<i>p-value</i> <sup>(1)</sup>	<u>Intervention</u> (n = 116)	<u>Control</u> (n = 128)	<i>p-value</i> <sup>(1)</sup>
<b><u>Psycho-social measures:</u></b>									
Sexual Risk Cognition questionnaire (SRCQ-22) – Median (range)	12 (0–72)	11 (0–55)	0.840	5 (0–55)	9 (0–56)	0.093	8.5 (0–68)	9 (0–59)	0.828
Situational Self-Confidence questionnaire (SSCQ) –Median (range)	7.98 (0.75–10.0)	7.96 (1.21–10.0)	0.772	8.69 (1.48–10.0)	8.31 (1.27–10.0)	0.050	8.40 (0.94–10.0)	8.46 (2.19–10.0)	0.847
Rosenberg Self-esteem scale – Median (range).	19 (10–33)	19 (10–34)	0.155	23 (15–30)	23 (13.3–30)	0.943	20 (10–32)	19 (10–32)	0.828
'Readiness to Change' questionnaire (% assigned to stage according to model) <sup>(2)</sup>									
Pre-contemplation	3.6% (6/167)	1.9% (3/161)	0.518 <sup>(3)</sup>	4.7% (6/127)	7.9% (10/126)	0.012 <sup>(3)</sup>	7.7% (8/104)	8.5% (10/118)	0.16 <sup>(3)</sup>
Contemplation	37.8% (63/167)	37.3% (60/168)		22.0% (28/127)	34.9% (44/126)		22.1% (23/104)	28.8% (34/118)	
Action	58.7% (98/167)	60.9% (98/161)		73.2% (93/127)	57.1% (72/126)		69.2% (72/104)	62.7% (74/118)	

<sup>(1)</sup> Comparing intervention and control at each stage of the trial.

<sup>(2)</sup> Explanation of each stage of the model provided in the text and see Chapter 4.

<sup>(3)</sup>  $\chi^2$  test for linear association comparing intervention and control at each stage.

**Table 14:** (cont'd) Results of the main and other secondary trial outcomes based on participant self-reports at baseline, 6 and 12 month follow up

	<b><u>Baseline</u></b>			<b><u>6 month</u></b>			<b><u>12 Month</u></b>		
	<u>Intervention</u> (n = 175)	<u>Control</u> (n = 168)	<i>p-value<sup>(1)</sup></i>	<u>Intervention</u> (n = 137)	<u>Control</u> (n = 139)	<i>p-value<sup>(1)</sup></i>	<u>Intervention</u> (n = 116)	<u>Control</u> (n = 128)	<i>p-value<sup>(1)</sup></i>
<b><u>Psycho-social measures:</u></b> (cont'd)									
HIV Attitudes questionnaire (HAQ) component scales – Median (range)									
Self-efficacy	4.5 (2.0–5.0)	4.75 (2.3–5.0)	0.204	4.75 (2.5–5.0)	4.75 (2.3–5.0)	0.943	4.8 (2.5–5.0)	4.5 (3.0–5.0)	0.828
Social norms	4.33 (2.3–5.0)	4.67 (2.3–5.0)	0.314	4.33 (2.3–5.0)	4.33 (2.0–5.0)	0.761	4.3 (2.7–5.0)	4.7 (2.0–5.0)	0.572
Communication skills	4.0 (1.0–5.0)	4.0 (1.7–5.0)	0.068	4.0 (1.7–5.0)	4.33 (2.0–5.0)	0.441	4.3 (2.3–5.0)	4.3 (1.7–5.0)	0.905
Self-labelling	3.33 (1.0–5.0)	3.33 (1.3–5.0)	0.236	4.0 (1.0–5.0)	3.66 (1.0–5.0)	0.74	4.0 (1.0–5.0)	3.8 (1.0–5.0)	0.255
Safer sex efficacy	4.0 (1.5–5.0)	4.0 (2.5–5.0)	0.705	4.0 (3.0–5.0)	4.0 (2.0–5.0)	0.906	4.0 (3.0–5.0)	4.0 (1.0–5.0)	0.137
Interpersonal barriers	4.0 (2.0–5.0)	4.0 (2.0–5.0)	0.070	4.0 (2.0–5.0)	4.0 (1.3–5.0)	0.857	4.0 (2.0–5.0)	4.2 (1.0–5.0)	0.941

<sup>(1)</sup> Comparing intervention and control at each stage of the trial.

month follow up) (see Table 14, p. 162). However, among the same restricted group of controls, there was little change (61.4% [78/127] at baseline, to 54.5% [55/101] at 6 month and 60.0% [57/95] at 12 month follow up). Comparing between arms at each follow up, these differences were not statistically significant ( $p = 0.243$  at 6 month and  $p = 0.755$  at 12 month follow up) and, after adjusting for baseline eligibility criteria (recruited with an STI and self-reported UAI in last 12 months) and whether the respondent reported having a regular partner/boyfriend, again the differences were still not statistically significant ( $p = 0.178$  at 6 month and  $p = 0.655$  at 12 month follow up). There was also a greater reduction among intervention participants than controls, in the proportion that reported any UAI in the last year, although this too was not statistically significant (60.9% [106/174] at baseline to 50.0% [58/116] to 12 month follow up compared to 62.7% [104/166] among controls at baseline and 59.4% [76/128] at 12 month follow up [ $p = 0.158$ ]) (see Table 14, p. 162).

There was no difference between the trial arms in median number of sexual contacts in the last month at baseline (Median = 3;  $p = 0.801$ ). Interestingly, both groups generally reported fewer sexual contacts in the last month at 12 month follow up (Median for interventions = 2.5 [range 0–25] and Median for controls = 2 [range 0–40];  $p = 0.869$ ) (see Table 14, p. 162).

There was no change in the median number of sexual contacts in the last year for controls (20 at baseline and 20 at 12 month follow up). However, in the intervention group the median increased by 3 (20 at baseline; 23 at 12 month follow up), but this was not statistically significant ( $p = 0.920$ ) (see Table 14, p. 162). Both groups reported AI with more sexual partners at 12 month follow up compared with baseline, but there was no overall change in the median number of UAI partners, either in the last month or the past year (see Table 14, p. 162). There was also no difference in the median number of AI partners at the 6 month follow up but, as a group, intervention men reported significantly fewer AI partners than the controls ( $p = 0.038$ ). This reduction was sustained at 12 month follow up for the

interventions, but because there was also a reduction between 6 and 12 months among the controls, it was no longer significant ( $p = 0.195$ ) (see Table 14, p. 162).

At both follow ups, among the men who reported UAI in the last month, there were reductions in both arms in the proportion that reported that the last episode involved a partner of unknown or different HIV status (see Table 14, p. 163). The reduction was larger among the intervention participants: 62.9% (39/62) reported at baseline that the last episode of UAI involved a partner of unknown or different HIV status compared with 43.8% (14/32) at 6 months and 48.4 (15/31) at 12 months. Among controls the proportions were 68.0% (34/50) at baseline, 65.1% (28/43) at 6 months and 46.2% (18/39) at 12 months. At no stage were the between arm differences statistically significant ( $p = 0.690$  at baseline;  $p = 0.099$  at 6 month and  $p = 1.00$  at 12 month follow up) (see Table 14, p. 163).

Although almost none of the secondary behavioural outcome measures achieved statistical significance, taken together there appears to be a small and fairly consistent improvement in the intervention arm overall. This might indicate a small, and most likely, transient beneficial intervention effect. One possible reason for the lack of significant differences between the study arms is that there were small improvements among controls in some measures.

Therefore, to assess the actual extent of changes within each study arm, and determine whether a larger intervention effect was being obscured by something else going on in the control group, selected behavioural measures were analysed for 'within-arm' changes between baseline and 12 month follow up. In this analysis each trial arm was analysed separately. These results are presented in Table 15.

The results in Table 15 confirm that behaviour change occurred in both the trial arms, with slightly more change reported by intervention participants. In respect to several measures, for

**Table 15:** ‘Within individual’ changes for selected self-reported outcomes compared (within study arm) between baseline and 12 month follow up

	<b><u>Baseline</u></b> (N = 343)		<b><u>12 Month</u></b> (N = 244)			
	<u>Intervention</u> (n = 175)	<u>Control</u> (n = 168)	<u>Intervention</u> (n = 137)	<u>Control</u> (n = 139)	<i>p-value</i> <sup>(1)</sup>	<i>p-value</i> <sup>(2)</sup>
<b><u>Sexual behaviour and sexual partnerships:</u></b>						
% reporting <i>all episodes of AI in last month condom protected</i>	48.8% (60/123)	61.4% (78/127)	63.3% (50/79)	60.0% (57/95)	0.268	0.031
Number of sexual contacts in last <i>month</i> – Median (range)	3 (0–60)	3 (0–45)	2.5 (0–25)	2 (0–40)	0.749	0.193
Number of sexual contacts in last <i>year</i> – Median (range)	20 (1–300)	20 (0–500)	23 (1–299)	20 (1–390)	0.399	0.505
Number of AI partners in last <i>month</i> – Median (range)	1 (0–12)	1 (0–30)	1 (0–7)	1 (0–20)	0.349	0.496
Number of AI partners in last <i>year</i> – Median (range)	3 (0–100)	4 (0–300)	6 (0–60)	5 (0–190)	0.405	0.242
% reporting <i>any UAI in the last month</i>	36.6% (63/172)	30.1% (50/166)	26.3% (30/114)	30.6% (38/124)	0.144	0.868
% reporting <i>any UAI in the last year</i>	60.9% (106/172)	62.7% (104/166)	50.0% (58/116)	59.4% (76/128)	0.063	0.280

<sup>(1)</sup> Comparing within individual changes among intervention participants between baseline and 12 month follow up.

<sup>(2)</sup> Comparing within individual changes among control participants between baseline and 12 month follow up.

**Table 15:** (cont'd) 'Within individual' changes for selected self-reported outcomes compared (within study arm) between baseline and 12 month follow up

	<u>Baseline</u> (N = 343)		<u>12 Month</u> (N = 244)		<i>p-value</i> <sup>(1)</sup>	<i>p-value</i> <sup>(2)</sup>
	<u>Intervention</u> ( <i>n</i> = 175)	<u>Control</u> ( <i>n</i> = 168)	<u>Intervention</u> ( <i>n</i> = 137)	<u>Control</u> ( <i>n</i> = 139)		
<b><u>Sexual behaviour and sexual partnerships:</u></b> (cont'd)						
Total UAI partners in last <i>month</i> – Median (range)	0 (0–4)	0 (0–3)	0 (0–4)	0 (0–3)	0.828	0.187
Total UAI partners in last <i>year</i> – Median (range)	1 (0–60)	1 (0–40)	1 (0–47)	1 (0– 21)	0.361	0.131
% reporting that last episode of UAI with partner of unknown or different HIV status <sup>(3)</sup>	62.9% (39/62)	68.0% (34/50)	48.4% (15/31)	46.2% (18/39)	0.035	0.152
<b><u>HIV testing and drug use:</u></b>						
% reporting having had an HIV test in last <i>year</i>	61.4% (108/175)	61.7% (103/167)	56.5% (65/115)	54.7% (70/128)	0.377	0.010
% reporting use of a Class A drug in last <i>year</i> (e.g. heroin, cocaine, crack)	36.6% (63/172)	36.5% (61/167)	24.5% (27/110)	31.7% (38/120)	0.344	0.322
% that reported used of ‘club’ drugs in last <i>year</i> (e.g. ecstasy, acid, poppers)	55.2% (95/172)	57.8% (96/166)	81.9% (95/116)	86.4% (108/125)	0.000	0.000

<sup>(1)</sup> Comparing within individual changes among intervention participants between baseline and 12 month follow up.

<sup>(2)</sup> Comparing within individual changes among control participants between baseline and 12 month follow up.

<sup>(3)</sup> Comparing intervention and control based on only those who reported any UAI in the last month.



intervention participants the 'within-arm' changes between baseline and 12 month follow up were either statistically significant or of borderline significance.

Among intervention participants there was a borderline significant reduction in the proportion reporting any UAI in the last year ( $p = 0.063$ ) and significant reduction in those reporting the last episode of UAI was with a partner of different or unknown HIV status ( $p = 0.035$ ) (see Table 15, p 170). This analysis demonstrated positive 'within-arm' changes among the control participants as well. For example, although there was little change in the proportion who reported that all episodes of AI in the last month were condom protected, between baseline and 12 month follow up (61.4% [78/127] vs. 60.0% [57/95]), the level of 'within-individual' change (positive ranks – men who answered negatively at baseline and positively at follow up) was higher and sufficient for this to be statistically significant ( $p = 0.031$ ) (see Table 15, p. 169). Overall the 'within-individual' changes are consistent with results from other studies with repeated measures of sexual behaviour (Dukers *et al.* 2001; Ekstrand & Coates 1990; Joseph *et al.* 1990; Kippax *et al.* 1997). They also confirm that behaviour change occurred in both groups of trial participants during the follow up. Given what is already known about the nature of sexual behaviour, this may simply reflect a 'regression towards the mean' in participants, reported behaviours over the course of the follow up (Morton & Torgerson 2003; Stephenson & Imrie 1998).

Table 16 summarises the effect of the intervention at 12 month follow up in respect to the main behavioural variables. Overall intervention men were slightly less likely than control men to report having engaged in UAI either in the last month ( $p = 0.471$ ) and when adjusted for eligibility at baseline, having a regular male partner, recreational drug use, this was sustained although not statistically significant ( $p = 0.718$ ). However, intervention men who reported engaging in UAI in the last month were slightly more likely than control men to have

**Table 16:** Key sexual behaviour and HIV risk reduction outcomes with crude and adjusted odds ratios for likelihood within the 12 month follow up based on participant self-reports

<b>Self-report at 12 month follow up</b>	<b>Intervention (n = 116)</b>	<b>Control (n = 128)</b>	<b>Odds Ratio (95% CI)</b>	<b>Adjusted Odds Ratio<sup>(1)</sup> (95% CI)</b>
Any UAI in the last month	27.2% (31/114)	31.5% (39/124)	0.814 (0.465–1.425)	0.891 (0.476–1.669)
Any UAI in the last year	50.0% (58/116)	59.4% (46/128)	0.684 (0.412–1.136)	0.683 (0.387–1.202)
Last UAI with partner of unknown or different HIV status <sup>(2)</sup>	48.4% (15/31)	46.2% (18/39)	1.094 (0.425–2.813)	1.602 (0.533–4.814)

<sup>(1)</sup> Odds ratios adjusted for eligibility at baseline (presenting with an STI), having a regular male partner/boyfriend and recreational drug use.

<sup>(2)</sup> Base is only those who reported any unprotected anal intercourse (UAI) in the last month.

had UAI with a partner whose HIV status was unknown or different to their own (adj p = 0.543).

## **7.6 Other secondary outcomes**

These were included mainly for their explanatory value. None of the measures grouped under this heading were specific targets for behaviour change in the workshop, except for STI/HIV transmission risk knowledge and uptake of prevention services (see Figure 6).

### *STI/HIV Knowledge*

There was a small, non-significant improvement in intervention men's mean scores in respect to STI/ HIV transmission risk knowledge through the 6 and 12 month follow ups. But as has been noted by other researchers, knowledge of STI and HIV transmission risks are generally high among gay men and an observation of only a small improvement most likely reflects the high baseline knowledge level (Hickson *et al.* 1999; King 1993).

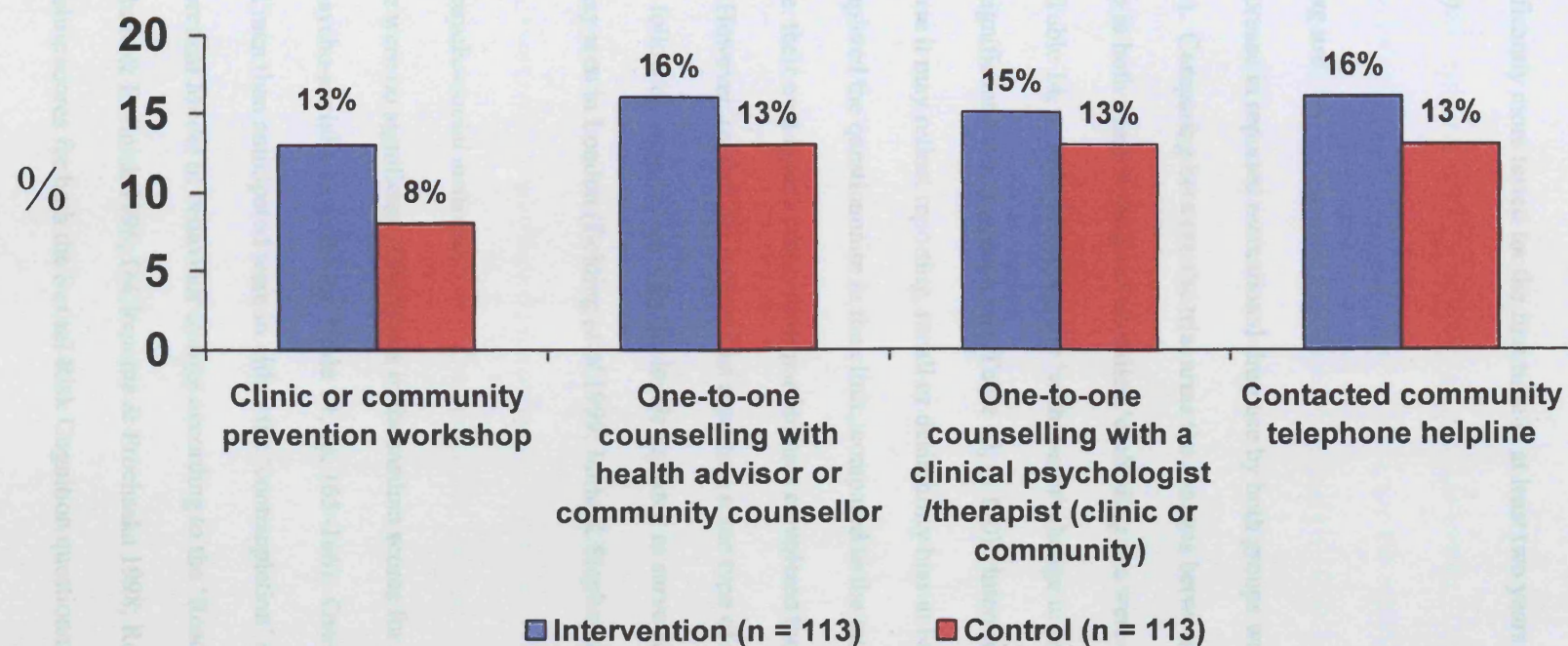
### *Uptake of prevention services*

One of the workshop exercises specifically focused on options for pursuing behaviour change outside the context of the intervention and a list of recommended reading and contact details of prevention services was included in the BIG Project Workbook (see Appendix 3). It is therefore disappointing that uptake of other prevention services at 12 months was generally low in both groups (see Figure 19). Uptake of more intensive prevention interventions, such as one-to-one counselling, was consistently higher among the intervention participants, although the differences did not achieve statistical significance.

### *HIV testing*

There was little difference in the proportions that reported having had an HIV test in the last year at baseline and at 12 months (see Table 14, p. 163). The proportions reporting an HIV

**Figure 19:** Percentage reporting uptake of other prevention interventions both within and outside the clinic by study arm, based on men completing baseline and both follow up questionnaires



test during the 12 month follow up were lower than baseline (56.5% [65/115] interventions and 54.7% [70/128] controls). Interestingly though, when the differences between baseline and 12 month follow up were analysed 'within-arm', they suggested there was actually a significant increase in testing among the control participants, that is fewer control men repeat tested, and significantly more tested for the first time in at least two years ( $p = 0.010$ ) (see Table 15, p. 170).

### *Recreational drug use*

The dramatic increase in reported recreational drug use by both groups was surprising (see Table 14, p. 164). Comparing between the trial arms the changes between baseline and 12 month follow up in both Class A drug and so-called 'club' drug use were not statistically significant (see Table 14, p. 164). However, the 'within-arm' change in reported 'club' drug use was highly significant for both groups (see Table 15, p. 170). Interpretation of this result is difficult because it may reflect reporting, recall or desirability bias at baseline when participants completed the questionnaire in the clinic, compared to the more relaxed surroundings (i.e. their own home) where most participants completed the follow up questionnaires. However, overall the proportions reporting some type of recreational drug use at 12 month follow up were in line with the levels reported in surveys of similar populations of gay men in London (Bolding *et al.* 1999; Imrie & Stephenson 2000).

### *Attitudinal and psycho-social measures*

At baseline there were no significant differences in the median scores for any of the attitudinal and psycho-social measures (see Table 14, pp. 165–166). Overall a higher proportion of all men than anticipated were in either the 'contemplation' or the 'action' stage of the Transtheoretical Model of behaviour change according to the 'Readiness to Change' questionnaire (Budd & Rollnick 1996; DiClemente & Prochaska 1998; Rollnick *et al.* 1992). The median baseline scores for both the Sexual Risk Cognition questionnaire (SRCQ-22) and

the Situational Self-Confidence questionnaire were higher than those reported in the original validation studies. This is noteworthy because both validation studies were undertaken in samples of gay men attending London GUM clinics (Shah *et al.* 1997; Wanigaratne *et al.* 1997). There were no statistically significant changes during follow up except in the median Situational Self-Confidence questionnaire, where intervention men's scores were significantly higher compared with controls at 6 months ( $p = 0.050$ ). The lower median score for the SRCQ-22 for intervention participants ( $p = 0.093$ ), and the significantly higher proportion of men assigned to the 'action' stage of the model ( $p = 0.012$ ) at 6 month follow up, provide weak evidence of a small intervention effect.

Improvements in the median scores on all the psycho-social measures were modest when considering both trial arms together, and again there was some indication that the improvements were not restricted to the intervention arm alone (see Table 14, pp. 165–166). A better method of testing the extent of any intervention effect was to use a 'within-individual' analysis. This involved comparing the mean change in 'within-individual' scores for all participants from baseline to each subsequent follow up. The results of this analysis are presented in Tables 17 and 18.

The only significant difference between the study arms in the combined mean score change was the HIV Attitudes questionnaire sub-scale relating to Interpersonal Barriers to condom-use. This difference was significant at 6 and 12 month follow ups (see Table 17), suggesting in the intervention group an increased confidence in negotiating condom-use with both regular and casual sexual partners. Comparing 'within-individual' changes in relation to the stage of the Transtheoretical Model, there was also a significant difference between the participants showing more movement among interventions than the controls (see Table 18). This was consistent with the between arms comparison illustrated in Table 14. The model's authors acknowledge that movement through each of the stages is not uni-directional, that is

**Table 17:** Attitudinal and psycho-social measures scores at baseline and each stage of follow up

Questionnaire <sup>(1)</sup>	Baseline Median (range) score		Difference in change in mean score between interventions and controls (95% CI) <sup>(2)</sup>	
	<u>Intervention</u> (n = 175)	<u>Control</u> (n = 168)	<u>6 month</u>	<u>12 month</u>
<b>Sexual Risk Cognition questionnaire (SRCQ-22)</b>	12 (0-72)	11 (0-55)	-1.15 (-3.80-1.49)	0.645 (-2.70-3.99)
<b>Situational Self-confidence questionnaire</b>	8.0 (0.8-10)	8.0 (1.2-10)	0.25 (-0.08-0.58)	0.02 (-0.35-0.39)
<b>Rosenberg Self-Esteem scale</b>	19 (10-33)	18 (10-34)	-1.10 (-2.57-0.37)	-0.22 (-1.33-0.89)
<b>HIV Attitudes questionnaire (HAQ) component scales</b>				
Self-efficacy	4.5 (2.0-5.0)	4.75 (2.25-5.0)	0.17 (0.02-50.32)	0.12 (-0.05-0.29)
Social norms	4.33 (2.33-5.0)	4.67 (2.33-5.0)	0.03 (-0.17-0.23)	0.02 (-0.19-0.24)
Communication skills	4.0 (1.0-5.0)	4.0 (1.67-5.0)	0.17 (-0.02-0.36)	0.23 (0.02-0.45)
Self-labelling	3.33 (1.0-5.0)	3.33 (1.3-5.0)	0.25 (0.00-0.49)	0.19 (-0.09-0.48)
Safer sex efficacy	4.0 (1.5-5.0)	4.0 (2.5-5.0)	0.08 (-0.11-0.26)	0.25 (0.03-0.47)
Interpersonal barriers	4.0 (2.0-5.0)	4.0 (2.0-5.0)	0.25 (0.06-0.45)	0.28 (0.07-0.49)

<sup>(1)</sup> Explanation of the scales, scoring and validation studies are covered in Chapter 5.

<sup>(2)</sup> Mean within-individual change from baseline. Intervention score minus control score.

**Table 18:** Assignment of participants according to the 'Readiness to Change' scale (Budd & Rollnick 1996; Rollnick *et al.* 1992a) at each stage of the trial

	<u>Baseline</u>		<u>6 month</u>			<u>12 month</u>		
	<u>Intervention</u> ( <i>n</i> = 167)	<u>Control</u> ( <i>n</i> = 161)	<u>Intervention</u> ( <i>n</i> = 127)	<u>Control</u> ( <i>n</i> = 126)	<i>p-value</i> <sup>(1)</sup>	<u>Intervention</u> ( <i>n</i> = 104)	<u>Control</u> ( <i>n</i> = 118)	<i>p-value</i> <sup>(1)</sup>
<b>Stage of Readiness to Change (according to model) <sup>(2)</sup></b>								
Pre-contemplation	3.6% (6/167)	1.9% (3/161)	4.7% (6/127)	7.9% (10/126)	0.03	7.7% (8/104)	8.5% (10/118)	0.16
Contemplation	37.8% (63/167)	37.3% (60/168)	22.0% (28/127)	34.9% (44/126)		22.1% (23/104)	28.8% (34/118)	
Action	58.7% (98/167)	60.9% (98/161)	73.2% (93/127)	57.1% (72/126)		69.2% (72/104)	62.7% (74/118)	

<sup>(1)</sup>  $\chi^2$  test for linear association comparing within individual changes from baseline.

<sup>(2)</sup> Stages of the model and movement between the stages are explained in the text and in Chapter 4.



towards the 'action' or 'maintenance' stages (DiClemente & Prochaska 1998; Prochaska *et al.* 1992). It is therefore not inconsistent that at 12 month follow up more intervention men were assigned to the pre-contemplation stage than at baseline or 6 months. According to Prochaska and DiClemente's interpretation this would suggest that some men had slipped up or relapsed back to the pre-contemplation stage (DiClemente & Prochaska 1998; Marlatt & Gordon 1985; Prochaska *et al.* 1992), and this would also be consistent with a small, transient beneficial effect immediately following the intervention. Combined with the sexual behaviour data, the progressive movement of more intervention men through the model's stages at 6 month follow up with no further change at 12 months supports the idea of a small, but transient intervention effect in the initial stages of the follow up period.

## **7.7 'On treatment' analysis**

To assess the BIG Project Workshop's generalisability to other settings, it was important to gauge how it performed in those who attended – the intervention's efficacy. The only specifically planned sub-group analysis was an 'on treatment' analysis in which participants who actually received the intervention ('on treatment' group) were compared to the controls. In respect to a small number of variables, they were also compared to the other group of intervention participants – those who did not attend the workshop. At the time the 'on treatment' analysis was undertaken we were already aware of the 'intention-to-treat' results. And therefore another important function of the 'on treatment' analysis was to estimate the extent of the potentially deleterious effect of the intervention in relation to the main trial outcomes, and to obtain additional insight into its failings.

It is important to sound a cautionary note about the value of an 'on treatment' analysis in this situation, as compared, for example, to a placebo-controlled drug trial. The key point is that comparing the results of those men who attended the intervention against the controls is not entirely without problems and therefore needs to be interpreted carefully and considered as

less than entirely persuasive. This is because it is not genuinely a case of comparing like-with-like. That is to say, men who attended the intervention were a self-selected group who opted to do so, while the control group was randomly assigned to that condition. In this sense, the results of the 'on treatment' analysis only give a measure of the efficacy of the intervention for those individuals who attended, and not its overall effectiveness. An alternative approach is to compare within the intervention arm between those who attended and those who did not. But this is not less problematic, because while it attempts to take account of the individual's choice (to attend or not), it cannot genuinely do so because these men were randomly assigned to this condition, and did not 'choose' to be invited to the workshop. There are limitations to both these approaches to 'on treatment' analysis as neither can fully account for the effect of individual's choice about attendance. With these caveats in mind, an 'on treatment' analysis can however, provide useful pointers about the intervention's efficacy and help understand the intervention's failure to deliver as hypothesised.

Somewhat reassuringly, overall the results of the 'on treatment' analysis were similar to the 'intention-to-treat' analysis (see Table 19). Comparing 'on treatment' men and the controls, there was little difference in the likelihood of having an STI diagnosed relative to the 'intention-to treat' results (for the broad definition 30.8% [53/172] of all intervention men had an STI diagnosed compared (see Table 11, p. 157) to 30.9% [38/123] in the 'on treatment' group (see Table 19, p. 181), (Adj OR for 'intention-to-treat' = 1.659 [95% CI 1.004–2.743] and Adj OR for 'on treatment' 1.686 [95% CI 0.979–2.901]). For the narrow definition, the proportions were 12.2% (21/172) of all intervention men compared to 11.4% (14/123) of the 'on treatment' men, with an adjusted OR for intention-to-treat of 1.844 (95% CI 0.851–3.993), and 1.651 (95% CI 0.709–3.843) for the 'on treatment' analysis. When the same analysis was performed using the alternative approach, that is restricted only to intervention men based on attendance or non-attendance, the results suggested that the

**Table 19:** New STI diagnosed at the clinic during the 12 month of follow up based on record review comparing 'on treatment' men and controls, with crude and adjusted odds ratios

	<b>'On treatment'</b> (n = 124)	<b>Control</b> (n = 168)	<b>Odds Ratio</b> (95% CI)	<b>Adjusted Odds Ratio<sup>(1)</sup></b> (95% CI)
<b>Any new STI diagnosed <sup>(2)</sup></b>	30.9% (38/123)	20.8% (35/168)	1.699 (0.996–2.897)	1.686 (0.979–2.901)
<b>New bacterial STI diagnosed <sup>(3)</sup></b>	11.4% (14/123)	6.5% (11/168)	1.833 (0.802–4.188)	1.651 (0.709–3.843)

<sup>(1)</sup> STI odds ratio adjusted for eligibility at baseline (presenting with an STI).

<sup>(2)</sup> A broad definition of new STI includes hepatitis B, first episodes of herpes and warts, early-latent syphilis, gonorrhoea, chlamydia and non-specific urethritis.

<sup>(3)</sup> A narrow definition of new STI includes only bacterial STI diagnosed at the clinic including primary and secondary syphilis, chlamydia and gonorrhoea.

**Table 20:** Analysis of self-reported main and other selected outcomes comparing 'on treatment' men and controls at baseline and 12 month follow up

	<b><u>Baseline</u></b>			<b><u>12 Month</u></b>		
	<u>'On treatment'</u> (n = 124)	<u>Control</u> (n = 168)	<i>p-value<sup>(1)</sup></i>	<u>'On treatment'</u> (n = 95)	<u>Control</u> (n = 128)	<i>p-value<sup>(1)</sup></i>
<b><u>Sexual behaviours</u></b>						
% reporting <i>all episodes of AI in last month</i> – <i>condom protected<sup>(2)</sup></i>	46.7% (42/90)	61.4% (78/127)	0.038	63.5% (40/63)	60.0% (57/95)	0.739
Number of sexual contacts in last <i>month</i> – Median (range)	3 (0–60)	3 (0–45)	0.639	2 (0–25)	2 (0–40)	0.691
Number of sexual contacts in last <i>year</i> – Median (range)	20 (1–300)	20 (0–500)	0.630	21.5 (1–299)	20 (1–390)	0.814
Number of AI partners in last <i>month</i> – Median (range)	1 (0–12)	1 (0–30)	0.749	1 (0– 7)	1 (0–20)	0.159
Number of AI partners in last <i>year</i> – Median (range).	3.5 (0–90)	4 (0–300)	0.324	5.5 (0–60)	5 (0–190)	0.911
% reporting <i>any UAI in last month</i>	39.0% (48/123)	30.1% (50/166)	0.132	25.5% (24/94)	31.5% (39/124)	0.368
% reporting <i>any UAI in last year</i>	62.1% (77/124)	62.7% (104/166)	1.000	47.4% (45/95)	59.4% (76/128)	0.079

<sup>(1)</sup> Comparing participants who completed the intervention and control at baseline and 12 month follow up.

**Table 20:** Analysis of self-reported main and other selected outcomes comparing 'on treatment' men and controls at baseline and 12 month follow up

	<u>Baseline</u>			<u>12 Month</u>		
	<u>'On treatment'</u> (n = 124)	<u>Control</u> (n = 168)	<i>p-value</i> <sup>(1)</sup>	<u>'On treatment'</u> (n = 95)	<u>Control</u> (n = 128)	<i>p-value</i> <sup>(1)</sup>
<u>Sexual behaviours: (cont'd)</u>						
Total UAI partners in last <i>month</i> – Median (range)	0 (0–4)	0 (0–3)	0.090	0 (0–3)	0 (0–3)	0.757
Total UAI partners in last <i>year</i> – Median (range)	1 (0–22)	1 (0–40)	0.927	1 (0–47)	1 (0–21)	0.294
% reporting that last episode of UAI with partner of unknown or different HIV status <sup>(3)</sup>	63.8% (30/47)	68.0% (34/50)	0.675	45.8% (11/24)	46.2% (18/39)	1.00
<u>HIV testing and drug use:</u>						
% reporting having had an HIV test in last <i>year</i>	60.5% (75/105)	61.7% (103/167)	0.903	53.7% (51/95)	51.6% (66/128)	0.787
% reporting use of a Class A drug in last <i>year</i> (e.g. heroin, cocaine, crack)	26.8% (33/123)	28.3% (47/166)	0.792	21.1% (19/90)	31.7% (38/120)	0.117
% that reported used of 'club' drugs in last <i>year</i> (e.g. ecstasy, acid, poppers)	52.9% (64/121)	57.8% (96/166)	0.470	81.1% (77/95)	86.4% (108/125)	0.353

<sup>(1)</sup> Comparing participants who completed the intervention ('On treatment') and control at baseline and 12 month follow up.

<sup>(2)</sup> Based on only those who reported any UAI in the last month.

negative intervention effect among those who attended ('on treatment') was no greater than among the others who did ( $p = 0.971$ ) (data not shown).

Unsurprisingly, reporting of reduced sexual risk behaviours was greater in the 'on treatment' group than in the intervention arm as a whole (see Table 14, pp. 162–163, and Table 20).

Comparing the main secondary outcome measures (Table 20) between the 'on treatment' group and the controls at 12 month follow up there were no significant differences. In the 'on treatment' group, the proportion reporting any UAI in the last month fell from 39.0% (48/123) at baseline to 21.3% (23/108) at 6 months and 25.5% (24/94) at 12 months with  $p$  values of 0.084 at 6 months and 0.368 at 12 months compared with the controls. At 12 month follow up fewer of the 'on treatment' men reported any UAI in the last year than controls (47.4% [45/94] vs. 59.4% [76/128];  $p = 0.079$ ). After adjusting for baseline eligibility and having a regular male partner the difference between the two groups was still not significant ( $p = 0.082$ ).

## 7.8 Conclusions

Overall, the main secondary sexual behaviour and HIV risk reduction outcomes pointed in the direction of a weak, most likely transient, beneficial effect in the intervention group.

However, it is the results of the clinical data relating to new STI diagnoses that are more persuasive because they were not subject to reporting bias, participant 'drop-out' or 'loss-to-follow-up'. In contrast, these showed that the intervention was more likely to be harmful, increasing the likelihood of acquiring a new STI, and this was of borderline statistical significance. Prior to this study, all previously published experimental evaluations of HIV prevention interventions with gay men had shown some degree of benefit, but they had also all relied exclusively on self-reported behavioural outcomes (Oakley *et al.* 1996). Being the first, and to date only, completed trial of this kind to incorporate biological endpoints, the results highlight the importance of including objective or externally measured outcomes,

which are on the whole more convincing indicators of effectiveness for health services planning (Aral & Peterman 1996; Aral & Peterman 1998; Cowan & Plummer 2003; Johnson *et al.* 2003; St Leger *et al.* 1992; Stephenson *et al.* 2000; Stephenson & Imrie 1998).

There was relatively little change in the knowledge and service uptake measures targeted in the Workshop. The lack of any significant change in overall STI/HIV knowledge is not entirely surprising, as gay men's knowledge in this area was already high. But given men's evaluation ratings of this exercise, it seems unlikely that there was no effect at all on STI/HIV transmission risk knowledge, but rather that it was not picked up by the questionnaire items which were repeated at each stage. The generally low uptake of other HIV prevention services in both trial arms is disappointing, but again not entirely surprising. It has been shown that intensive face-to-face prevention interventions tend to attract only a small proportion of the men who might benefit from them, even when men are referred directly from clinical services (Devlin *et al.* 2003).

The rather patchy picture that emerges from the attitudinal and psychometric measures confirms the suggestion that any positive behavioural effect was weak and most likely transient. The fact that a high proportion of men at baseline were already in the 'action' stage according to the Transtheoretical Model of behaviour change was unanticipated and as a consequence it is possible that the intervention's positive impact was weaker than expected in these men. However, as intermediate explanatory measures of how and whether the intervention worked, these measures suggest that, in relation to the hypothesised key cognitive variables linked to high-risk sexual practice, the intervention failed to have a significant impact.

The results of matching participants to the regional database of STI diagnoses and the postal urine survey indicated that systematic ascertainment bias was unlikely and that the clinic

record review did not miss a significant number of new STI diagnoses. Analysis of the effects of the intervention based on an 'on treatment' analysis and the extended record review demonstrated reassuringly that any deleterious effect associated with the intervention was not significantly more pronounced among those who attended and that it attenuated over time. Nevertheless, accepting that the self-reported results were accurate and not subject to systematic reporting bias leaves open the question of how the results can be explained. This is the context and topic of the next chapter.



## **Chapter 8**

### **Explanations for the Randomised Controlled Trial results**

#### **8.0 Introduction**

The main trial results described in the previous chapter were unanticipated and initially a cause for concern. However, both the extended clinic record review and ‘on treatment’ analysis provided some reassurance that the negative effect in the intervention group was small and attenuated over time. But what these additional analyses could not explain was the apparent contradiction between the STI and the behavioural endpoints, and why this occurred. The purpose of this chapter is to explore possible explanations for this.

Six hypotheses were investigated. Three were *a priori* hypotheses, that is they originated in prior research and opinion found in the published literature, and three were derived from the

trial's process and quality assurance evaluations. The six hypotheses described in this chapter are illustrated in Figure 20. Specific data were used to test each hypothesis and then triangulated with other data to develop a more complete picture.

**Figure 20:** Six hypotheses investigated to explain trial results

<i>A priori</i> hypotheses	Hypotheses derived from Process & Quality Assurance evaluation
<b>1) Unintended effect attributable to trial procedures:</b> Participant retention and follow up procedures produced an unintended intervention effect specifically among controls that was reflected in their self-reported behaviour	<b>4) Mis-matched expectations &amp; perceptions:</b> Facilitator and participant expectations of the workshop and value of specific exercises were mis-matched, resulting in an intervention that did not meet the participants' actual prevention needs
<b>2) Inappropriateness of intervention content/theoretical base:</b> The models used to develop the intervention and assumptions made about the target population meant the wrong issues were covered in the workshop for the men recruited to the trial	<b>5) Intervention as a socialisation vehicle:</b> The intervention provided a socialisation vehicle that re-enforced rather than challenged men's high-risk sexual behaviour
<b>3) New regular partnerships:</b> Intervention men were more likely after attending the workshop to acquire new regular partners with whom they engaged in high-risk sex that resulted in more incident STI	<b>6) Risk compensation:</b> Men in the intervention group increased condom-use but compensated by acquiring more new partners with whom they had AI which resulted in more incident STI

### 8.1 Hypothesis 1 – Unintended effect attributable to trial procedures

General improvement in self-reported behaviour outcomes in both trial arms, without an equivalent reduction in incident STI, is not without precedence and explaining such anomalies has been the subject of considerable discussion in the research literature (Hopperus-Buma *et al.* 1995; Otten *et al.* 1993; Turner & Miller 2000; Wiktor *et al.* 1990; Zenilman *et al.* 1995). One explanation, only partially explored in the literature, is that in trials of brief complex behavioural interventions, follow up and participant retention procedures can themselves lead to an unintended intervention effect that is more pronounced

in one group than the other. In only one case have investigators published results of their attempt to assess the extent to which simply being involved in a study influenced subsequent self-reported behaviour, a so-called 'Hawthorne effect'. This was in Project RESPECT, a large trial in the United States, completed at approximately the same time as the BIG Project was in recruitment (Kamb *et al.* 1998a).

Project RESPECT used a four-arm randomised design to evaluate two interventions against an active control group, and a fourth group whose only follow up was through record review of clinic reattendances and STI diagnoses (Kamb *et al.* 1998a). The Project RESPECT team found significant improvements in self-reported behaviours in both intervention groups relative to both control groups. But they also noted a non-significant improvement in the main trial outcomes in the 'active controls' relative to the 'record review only' group (Kamb *et al.* 1998a). The trial procedures in Project RESPECT were considerably more intensive than those in the BIG Project. For example, active follow up involved planned clinic visits for HIV and STI screening, face-to-face interviewer administered follow up questionnaires and financial incentives for continued participation (Kamb *et al.* 1996; Kamb *et al.* 1998a; Kamb *et al.* 1998b). The investigators concluded there was almost certainly some form of participation effect in the 'active control' group compared to the 'record review only' group, but they were unable to determine if the effect was attributable to specific trial procedures or a more generalised participation effect (Personal Communication: Dr Mary L Kamb, CDC Global AIDS Program, Hanoi, Vietnam, September 2001). Based on the Project RESPECT experience, one hypothesis that may partially explain the differences in the self-reported and objectively derived results in the BIG Project is an unintended intervention effect of the trial procedures that specifically influenced the control group and contributed to their reported improvements in self-reported HIV risk behaviours. Some of this improvement would not have been picked up in global measures such as UAI in the last year. These measures are relatively insensitive to individual's general behaviour change or personal risk reduction,

whereas a measure like having had an HIV test in the last year, for example, can pick up changes in protective health behaviours that may in turn be reflected in reporting whether the last episode of UAI involved a partner of unknown or discordant HIV status.

#### *Maintaining contact with the BIG Project team*

Although less involved than Project RESPECT, the BIG Project trial procedures were nonetheless intensive and demanding of participants. High follow up rates are essential in individually randomised trials to ensure validity of the results (O'Leary *et al.* 1997). To achieve acceptably high follow up rates in the BIG Project, considerable effort was made to maintain contact with highly mobile participants, and this may have produced an unintended effect. The BIG Project's complete follow up and retention procedures are described in Figure 21. Overall 93.8% (322/343) of all randomised participants had some form of contact

**Figure 21:** Follow up and retention procedures in the trial

<b>Follow up Procedures for All Participants</b>	<b>Retention Procedures for All Participants</b>
<b>Four options to provide follow up data:</b> All involved either returning to the clinic (with or without a screen) or a postal questionnaire	<b>Condom-requests:</b> Unlimited condoms & water-based lubricant were available on request and delivered by post or retrieved from the clinic (see Appendix 6)
<b>Postal follow up:</b> 3 attempts were made to contact participants with postal questionnaires before they were treated as lost to follow up	<b>Participant newsletter:</b> A participant newsletter sent out by post periodically to all participants (see Appendix 11)
<b>Active clinic follow up:</b> Monitoring of clinic appointment lists to identify study participants attending in order to invite them to complete a follow up questionnaire	<b>Identification of prevention services:</b> Assistance was available to all participants wishing to access either clinic-based or community-based prevention services
<b>Contact details:</b> All promotional materials and letters contained telephone and email contact details for the trial co-ordinator (JI) and participants were encouraged to contact the research team regarding any issues related to the study	

with the BIG Project or the clinic during the 12 month follow up period. The frequency and intensity of these contacts varied. Some men were contacted only once after enrolment, when they were sent a copy of a participant newsletter (see Appendix 11), while others, for example men with HIV or men having ongoing treatment, attended the clinic regularly throughout the study.

### *Follow up questionnaires*

Monitoring data from the distribution and return of follow up questionnaires, participant focus groups and participants' unsolicited comments on returned questionnaires provided substantial insight into the differential effect of the trial follow up procedures in each group. The majority of participants were followed up by postal questionnaires. At each follow up stage, about 21% of participants returned to the clinic to complete the questionnaire. At 6 month follow up, the majority of participants who returned a postal questionnaire did so after one request, while at 12 month follow up it required an average of 2 requests to obtain a response from intervention participants, but only one for the controls.

In the participant focus groups and in unsolicited comments, participants in both arms expressed opinions about the value they attached to the follow up questionnaires. Many felt that they provided an opportunity for personal reflection on events and sexual practice, and in some cases they served as 'triggers' to action. On the whole, controls regarded the follow up questionnaires more positively than the interventions, as the following extract from a control participants' focus group illustrates:

I        'So, do you feel it was a positive experience or...?'

R2      'Yes, I do. I do in the sense that I quite enjoyed the questionnaires. There's about three so far have come in and I've quite enjoyed filling them in, in the sense that it's made me think about things. I mean I've been on courses before where it made you look at yourself and reassess what you wanted and, you know, look at what you thought you were doing negatively and try

to change. But I found the questionnaires coming as they did, you know, it made you think ... have I done this, have I done that kind of thing. And that was really quite good for me.

- R4     Hmm. I, I mean, I just think, I wonder if what I covered myself, what I've gained from the questionnaires, the newsletters, over the eighteen months, I've wondered if what I've got is what would have been given perhaps in a shorter period of time over the workshop? You know, I've done other studies, like [—] ... and you know, I really didn't feel like I got anything out of them. But it's not like that with this one. I think I've achieved something good for me.  
(FG # 2 – Controls)

In this case the participants describe how simply ongoing contact with the BIG Project and the follow up questionnaires themselves may have had positive influences. There were more extracts from the qualitative data that support this idea. These come mainly from the comments section at the end of each questionnaire. Arguably these comments are the more instructive because they were made at the time the participants were completing the questionnaires, when the experiences and impact were fresh in their minds. The example below is not typical, but it illustrates powerfully how receipt of a questionnaire and the process of completing it prompted significant self-reflection.

After being out last night and getting completely off my face and going with some guy, I got home and found this questionnaire and a big brown envelope full of condoms. This has really made me think. I don't know if it's going to mean I change (I hope so), but it has *really* made me think!

(BIG 089 F1)

### *Condom-requests*

For most participants, the condom-request scheme was the most regular contact with the BIG Project. Although certainly not its main aim, the extract above suggests the condom-request scheme may also have indirectly contributed to some participants' self-reflection processes. The actual aim of the condom-request scheme was to ensure the BIG Project team was informed of participants' current postal contact details. However, analysis of the condom-requests monitoring data suggests that it may have also indirectly contributed to the hypothesised unintended intervention effect.

In total, 27,286 condoms and lubricant sachets were distributed. Overall 80.4% (275/342) of participants requested condoms at least once during follow up. Significantly more of the control than intervention participants requested condoms (75.9% [133/175] interventions vs. 85.1% [143/168] controls;  $p = 0.04$ ). The median number of condoms received among all randomised men was 72 (range 0 - 624) (Median for interventions 72 [range 0–420], Median for controls 78 [range 0–624] [ $p = 0.734$ ]). However, because significantly more controls used the condom-request scheme, further analysis was undertaken to look at whether the combined effect of frequency of contact with the BIG Project and numbers of condoms received were associated with more positive trial outcomes in the group.

Among all men, comparing those who requested condoms with those who did not, 'condom-requesters' were non-significantly less likely to report any UAI in the last 12 months (OR 0.845; 95% CI 0.515–1.388) and less likely to have had a new STI diagnosed (OR 0.776; 95% CI 0.648–2.311). Additional analysis was undertaken to explore whether greater frequency of condom-requests, and, therefore, greater numbers of condoms received, could have had an influence on the main trial outcomes. All men who requested condoms were divided into two groups: those who had fewer condom-requests and, therefore, received fewer condoms, that is less than the mean, and those who requested condoms more frequently, and therefore received more condoms. This analysis showed that the men who received more than the mean were less likely to have a new STI diagnosed (OR 0.936; 95% CI 0.531–1.650) and also less likely to report any episodes of UAI in the last 12 months (OR 1.207; 95% CI 0.714–2.042). Although neither of these results was statistically significant, both point to the possibility that the condom-request scheme may have indirectly contributed to the overall trial results. It also appears that this contribution was linked to the frequency of participants' contact with the scheme, hence the BIG Project.

### *Participant newsletter*

The Participant Newsletter was produced roughly quarterly during the first 18 months of recruitment and every 6 months thereafter (see Appendix 11). The newsletters were distributed by post with a condom-request enclosed. The newsletters were intended to keep participants informed and to give them a sense of belonging to something of importance, without providing any information that might influence their involvement in the study or the trial's outcome. However, in the participant focus groups it became apparent that the newsletters might have done slightly more than originally intended, particularly for those in the control group.

I      What about other kinds of contact with the project?

R3     What, like the newsletters and the condoms?

I      Yes. OK, how about we talk about those for a bit then?

R3     I guess for me, I think they gave me a sense of ... Well, my first reaction is belonging, but perhaps that's not quite the word. A sense of participation in the project, I suppose of doing something worthwhile and something good for myself.

(FG # 2 – Controls)

### *Summary*

Considering the different trial follow up and retention procedures separately, it is not possible to identify any one factor as being more likely to have had an impact than the others.

However, when the effects are considered together, there does seem to be persuasive evidence that they produced an effect of some kind that was generally greater in the control group.

That both trial groups had equal potential for exposure to the different follow up and retention procedures does not preclude the possibility that the impact was greater in one group than the other. Men in the intervention group might well have been less influenced by the trial follow up and retention procedures because they knew already that they had received the actual intervention. But for men in the control group, the regular reminders and continued contact with the BIG Project may have provided them with a sense of continuing involvement



that was different from that experienced by the intervention group. And as such, it may have provided them with 'their own intervention', an unintended effect that genuinely contributed to behaviour changes that they reported in the follow up questionnaires. Controls greater use of the condom request scheme, overall lower numbers of sexual contacts and improved health behaviours, such as, uptake of HIV testing, are all factors that could be associated with fewer STI diagnoses, although admittedly, the changes in the main self-reported behaviour measures do not support this.

## **8.2 Hypothesis 2 – Inappropriateness of intervention content/theoretical base**

Researchers' understanding of the role and importance of theory in designing sexual health and HIV prevention interventions has advanced considerably since the initiation of the BIG Project (Campbell *et al.* 2000; Fishbein 2000; Nazareth 2003; Prochaska *et al.* 1994a; Stephenson *et al.* 2000; Sutton 1998; Sutton 2003; UK Medical Research Council 2000). But exactly what place behavioural change theory should occupy in relation to the design of interventions, the selection of outcomes and approaches to data analysis continues to be vigorously debated (Fishbein & Jarvis 2000; King 1999; Stephenson *et al.* 2000; Sutton 2003; Wight & Obassi 2003). Two areas of important debate with direct relevance to the BIG Project Workshop are the use of theory in designing interventions and the relevance of the Transtheoretical Model of behaviour change in designing what are essentially generic interventions.

The thinking underlying the BIG Project Workshop content was essentially based on one theory – the Transtheoretical Model of behaviour change. But the actual intervention incorporated elements from other health and behavioural change models (Billington & Wanigaratne 2000; King 1999; Prochaska & DiClemente 1986; Prochaska *et al.* 1994a). This somewhat eclectic approach to behavioural change theories has been referred to as 'cafeteria style' use of theory, that is selecting 'parts' of theories or models to design complex

behavioural interventions and leaving out others (Stephenson *et al.* 2000; Sutton 2003). So-called cafeteria style selection of theory has been strongly criticised, as have the resulting interventions, because they almost always lack a clear critical pathway explaining how the intervention should bring about behavioural change in practice (King 1999; Stephenson *et al.* 2000; Sutton 2003). It is usually very difficult to investigate or explain why an intervention results in a particular outcome, or whether the intervention is even in fact likely to be responsible for the observed outcome.

The second area of debate concerns the actual utility of the Transtheoretical Model itself as a basis for designing what are, effectively, generic HIV prevention and sexual health interventions (Sutton 2000; Sutton 2001; Sutton 2003). The Transtheoretical Model has been demonstrated to be useful in HIV prevention interventions in some settings (CDC AIDS Community Demonstration Projects Research Group 1999; Schnell *et al.* 1996; Schnell *et al.* 1993). However, its appropriateness in relation to other generic sexual health and HIV prevention interventions has recently been called into question because of 'serious conceptual and measurement problems' (Sutton 2003 p. 58).

In light of this criticism, and with the benefit of hindsight, it would be easy to attribute the BIG Project results to choosing the wrong model and adopting an overly eclectic approach in deciding the content of the intervention. But this would be short-sighted, because even among those who argue for restricting interventions to a single model or theoretical bases, there is agreement that theory and models alone cannot identify what constitutes an effective intervention (O'Leary *et al.* 1997; Shain *et al.* 1999; Stephenson *et al.* 2000; Sutton 2003). This is where the key roles of formative research, piloting and feasibility studies come into play (Kelly *et al.* 1993; Kelly 1994; Middlestadt *et al.* 1996; Peterson & DiClemente 1994; Ramos *et al.* 1995; Shain *et al.* 1999; Stephenson 2003; Stephenson *et al.* 2000; Stephenson & Imrie 1998; Wight & Obassi 2003). Although as an intervention the BIG Project Workshop

did not conform to purist views about the use of theory, it had been developed based on significant first-hand experience of 'Changing personal sexual practice', and extensive formative, piloting and feasibility research (Billington *et al.* 1997; Wanigaratne *et al.* 1992; Wanigaratne *et al.* 1997; Williams *et al.* 1993). It was therefore arguably an appropriate candidate intervention for an RCT evaluation.

### *Targeting of the intervention relative to the model*

The attitudinal and psychometric data indicated that most of the trial participants were assigned to a different stage of the Transtheoretical Model than were targeted by the BIG Project Workshop. According to the theory of stage models of behaviour change, behavioural modification occurs through a sequence of discrete steps, and different factors are important at each stage of this process (Sutton 2000; Sutton 2003). To be effective, different (stage-matched) interventions should be used with people at different stages of the process (DiClemente & Prochaska 1998; King 1999; Prochaska & DiClemente 1986; Prochaska *et al.* 1994a; Prochaska *et al.* 1994b; Sutton 2003). However, to fit the routine of a busy GUM clinic, it was necessary that the BIG Project Workshop be tailored and delivered in a one-size-fits-all (generic/generalisable) format that focused on the stage it was presumed most participants would be in. In practice, this meant the BIG Project Workshops targeted the 'pre-contemplation' and 'contemplation' stages, with only two exercises that related to the 'action' and maintenance stages (see Figure 3, p. 69 & Figure 6, p. 86). However, in reality, based on the 'Readiness to Change' questionnaire, at baseline nearly three-fifths (59.8%; 196/328) of all men were already in the 'action' stage (see Table 14, p. 165). This could be taken to suggest that it may not be the BIG Project Workshop *per se* that failed to perform, but that it was inappropriately targeted for the group of men recruited to the study. As a consequence of poor targeting, the majority of men probably gained relatively little from the BIG Project Workshops in terms of helping them to progress further with their behaviour change because they were already in a more advanced stage relative to the model.

### *Most valuable exercises*

This draws into question the appropriateness of the actual intervention content, which can be explored from the participants' rating of individual exercises. Using open-ended questions, participants were asked in the Participant Workshop Evaluation questionnaire to list the three most helpful aspects of the workshop. Exercises specifically linked to Transtheoretical Model's cognitive-behavioural change approach were ranked as 'Most useful aspect of the workshop' by less than one-quarter (30/121) of respondents. But equally, only 27.6% (34/123) found any of these exercises difficult or challenging (see Table 8, p. 137). By implication this suggests the model and the cognitive-behavioural approach did not adequately engage participants, perhaps because the participants were in a different stage of the change process as discussed above. If this were so, then the intervention content would not have targeted the right issues and the participants would not have felt sufficiently challenged.

There is additional evidence to support these contentions in the baseline Sexual Risk Cognition and Situational Self-Confidence questionnaire responses. Study participants' mean baseline scores were on the whole higher than those of the subjects in the original validation studies (see Table 14, p. 164) (Shah *et al.* 1997; Wanigaratne *et al.* 1997). This is important because the original validation studies were undertaken with samples from among gay men attending London GUM clinics, and these validation studies were relied upon heavily in determining the original content of the 'Changing personal sexual practice' intervention that became the BIG Project Workshop (Shah *et al.* 1997; Wanigaratne *et al.* 1997).

### *Targeting the wrong prevention needs*

Evidence from participant focus groups supports the original hypothesis that by relying on the underlying premise of the Transtheoretical Model, and focusing on specific stages of the model, some of the workshop exercises targeted inappropriate HIV prevention issues for the

men involved in the study (Prochaska *et al.* 1994a; Prochaska *et al.* 1994b). As the comments in one focus group suggest, several men were offended by the approach taken by facilitators in the intervention. They considered it 'pathologising' and felt that the approach attributed problems to them that they themselves did not feel existed. Others felt that the cognitive-behavioural approach used had little attraction or relevance for them as individuals.

I     How about the BIG Project Workshop? Can you recall anything about the BIG Project Workshop?

R3    I mean in terms of the actual workshop I have to say that I found some of it a little bit trite, and I actually objected on the day because they were – I think there was a woman leader within our workshop. She was making generalisations about our sexual behaviour, which ultimately I objected to ... The stuff she was saying, it just didn't apply to me ... And then, I think I found a lot of the, particularly the preparatory stuff about creating a safe space and being touchy feely and all this sort of thing, I just found that very trite and really trying. But I have to say, I mean, my biggest objection was this massive assumption they started to make about our sexual behaviour. And I, you know, I ultimately came to the, or I had to conclude that, you know, maybe the recruitment process or screening for recruitment wasn't quite what it should have been. Because actually, I think, I'm not sure that the research was actually aimed at somebody like me just because of my personal choices in life and the kind of stuff I do, you know, sex stuff ... I've got that stuff sorted out in my mind, and they just kept implying I didn't.

R5    I guess I didn't feel I got much from it, you know. It was because ... I mean on the sex side of it, I didn't think I had any sort of, like, problem beforehand to solve. And after I just carried on as normal, having safe sex. It hasn't sort of like increased my drive to be safe. I don't think? It hasn't, because that was always there beforehand, and the filling in of the questionnaires every six months or whatever, I mean that half an hour of filling in the form did probably more good ... Well, it did! Made me to think, right, it's time to go and have a test, just for the fact that it is six or nine months or whatever.

(FG#2 – Interventions)

Perhaps ironically, one participant related in a focus group how he had taken the skills acquired in the workshop and, using the BIG Project Workbook, had successfully quit smoking. He did not appear to be aware that the Transtheoretical Model of behaviour change was originally developed in the context of smoking cessation, and simply found the model and problem-solving approach helpful (Prochaska & DiClemente 1983; Sutton 2000). However, this is a point worth highlighting because this participant used the skills acquired to achieve behaviour change, albeit unrelated to sexual risk behaviour. However, such unintended positive consequences of interventions are rarely described in the literature (Moher *et al.* 2001; Schultz *et al.* 1995; Schultz 1995).

## *Summary*

Since the BIG Project's inception, understanding of how behavioural change theories and models should contribute to the development of prevention interventions has moved forward. Several strands of evidence drawn from participant baseline and follow up questionnaires, Participant Workshop Evaluation questionnaires and focus groups appear to confirm that the eclectic use of different behaviour change theories and the resultant intervention content was inappropriately targeted and sub-optimal for the group recruited to the study. They also support what other researchers have concluded about the questionable utility of the Transtheoretical Model of behaviour change in designing what are essentially generic sexual health and HIV prevention interventions (Sutton 2003).

### **8.3 Hypothesis 3 – New regular partnerships**

About the time the BIG Project was initiated a number of published reports concluded that condom-use for anal sex with casual partners had become more or less a norm among gay men, but that practices with regular partners were more likely to involve UAI and, that as a result, the main source of sexual HIV risk involved sex between regular partners (King 1993). This idea seems to be confirmed by evidence from several HIV sero-converter studies that showed recent sero-converters were more likely to be in a relationship with a regular male partner/boyfriend than their HIV negative controls (Gilbart *et al.* 2000; King 1993; Ostrow *et al.* 1995; Williams *et al.* 1996). So-called 'negotiated safety' agreements were also growing in popularity among men in primary relationships (Billington *et al.* 1995; Kippax *et al.* 1993). Retained materials from each of the BIG Project Workshops revealed that the personal sexual goal most commonly described by participants in 'Setting personal sexual goals' exercise was to acquire a boyfriend or RMP. Taken together these four factors suggested the possibility that some of the trial results might be a consequence of participants engaging in high-risk sexual practices with new regular partners. It was reasonable then to hypothesise based on the literature that if more men in the intervention arm acquired a new regular partner than in

the control group, based on their expressed goals and new-found self-esteem and self-confidence, then part of the difference in the STI results might be attributable to engaging in high-risk sex with their new regular partners acquired during the follow up period. If this were true it might also offer a partial explanation for the higher number of intervention men attending for STI screening during the follow up – as part of establishing a new relationship. However, the data to explore this hypothesis are limited and come from the questionnaires and clinic record review.

#### *Regular partners and new regular partner acquisition*

At baseline 48.7% (164/337) of all randomised men reported a regular male partner/boyfriend (48.5% [83/171] of interventions and 48.8% [81/161] of controls). The average time with a regular partner was between 6 months and one year, although about 40% of men indicated they had been with their regular partner for more than one year (39.8% [33/83] of interventions and 40.7% [33/87] of controls).

Patterns of new regular partner acquisition during the follow up were examined for all participants and then by study arm, using data only from men who responded to the 'regular partnership' item in all three questionnaires (N = 211). Overall 20.6% (51/211) reported no regular male partner/boyfriend at any point during the study (27.9% [29/104] of interventions and 20.6% [22/107] of the controls). At 12 month follow up, 30.3% (64/211) reported that they were still with the same regular partner as at baseline (33.7% [35/104] of interventions and 27.1% [29/107] of the controls) and 33.7% (71/211) reported acquiring at least one new regular partner between baseline and 12 month follow up. More men in the control group reported acquiring a new regular partner during the study than interventions, and this was of borderline statistical significance (39.4% [28/71] of interventions vs. 60.6% [43/73] of controls;  $p = 0.060$ ).

### *Regular partners and the trial endpoints*

Although these results immediately refuted the original hypothesis, the remaining planned analysis was undertaken to see whether acquisition of a new regular partner was associated with an increased likelihood of negative trial outcomes. This involved deriving a composite variable to make crude comparisons of the likelihood of the main trial outcomes based on whether or not men acquired a new regular partner during follow up. In the analysis, the reference group was men who did not acquire a new regular partner ( $n = 140$ ). The reference group included men who remained with the same regular partner throughout the study ( $n = 51$ ), men with no regular partner at any point during the study ( $n = 64$ ) and men who reported a regular partner at baseline, but whose baseline partnership broke down at some point during the study and they did not report a new regular partner in any subsequent follow up ( $n = 25$ ). Selection of these participants was based on the assumption that increased risk of negative outcomes was linked to acquisition or change of a regular partner, and not sex with casual partners (King 1993). The comparison group consisted of men ( $n = 71$ ) who reported at least one new regular male partner/boyfriend during follow up. The results of the analysis are presented as crude and adjusted ORs in Table 21, and by trial arm separately in Table 22.

The men who acquired a new regular partner during follow up were more likely to have had an STI diagnosed and to report UAI in both the last month and the last year than men whose risk remained constant (Table 21). Adjusting for total number of sexual contacts and total number of AI partners had little effect on the adjusted ORs, which were still not statistically significant. However, when the same analysis was performed with the data broken down by study arm, there was a divergence in the results that appeared to suggest that among the intervention group acquisition or change of RMP reduced the likelihood of acquiring an STI, but not of having UAI, compared to the controls (see Table 22). These results need to be treated with considerable caution and are presented for completeness, but are nonetheless surprising because they ran completely contrary to the original hypothesis.



**Table 21:** Acquisition of a new regular partner – and the likelihood of the main trial endpoints at 12 month follow up

Acquired a new regular partner and ...	All Participants (N= 71)	Odds Ratio (95% CI)	Adjusted Odds Ratio <sup>(1)</sup> (95% CI)
Any new STI diagnosed <sup>(2)</sup>	29.6% (21/71)	1.223 (0.646–2.316)	1.137 (0.568–1.428)
New bacterial STI diagnosed <sup>(3)</sup>	7.0% (5/71)	0.646 (0.223–1.871)	0.440 (0.136–1.428)
Any UAI in the last year	39.4% (28/71)	1.637 (0.897–2.989)	1.377 (0.712–2.663)
Any UAI in the last month	64.8% (46/71)	1.517 (0.849–2.712)	1.183 (0.611–2.291)

<sup>(1)</sup> Adjusted for total number of sexual contacts in last 12 months and total number of AI partners in last 12 months.

<sup>(2)</sup> A broad definition of new STI includes hepatitis B, first clinical episode of herpes and warts, primary and secondary syphilis, gonorrhoea, chlamydia and non-specific urethritis.

<sup>(3)</sup> A narrow definition of new STI includes only bacterial STI diagnosed at the clinic, including primary and secondary syphilis, chlamydia and gonorrhoea.

**Table 22:** Acquisition of a new regular partner – and the likelihood of the main trial endpoints at 12 month follow up for intervention and control arms separately

Acquired a new regular partner and ...	Interventions (N = 28)	Odds Ratio (95% CI)	Adjusted Odds Ratio <sup>(1)</sup> (95% CI)	Controls (N = 43)	Odds Ratio (95% CI)	Adjusted Odds Ratio <sup>(1)</sup> (95% CI)
Any new STI diagnosed <sup>(2)</sup>	28.6% (8/28)	0.794 (0.307–2.049)	0.362 (0.099–1.321)	30.2% (13/43)	2.747 (0.974–7.752)	2.541 (0.889–7.264)
New bacterial STI diagnosed <sup>(3)</sup>	7.1% (2/28)	0.424 (0.088–2.045)	0.075 (0.006–0.946)	7.0% (3/43)	1.463 (0.281–7.611)	1.401 (0.198–9.924)
Any UAI in the last year	35.7% (10/28)	1.447 (0.576–3.636)	0.804 (0.263–2.460)	41.9% (18/43)	1.731 (0.768–3.900)	1.976 (0.790–4.942)
Any UAI in the last month	57.1% (16/28)	1.333 (0.564–3.153)	0.506 (0.165–1.551)	69.8% (30/43)	1.505 (0.671–3.380)	1.869 (0.757–4.617)

<sup>(1)</sup> Adjusted for total number of sexual contacts in last 12 months and total number of AI partners in last 12 months.

<sup>(2)</sup> A broad definition of new STI includes hepatitis B, first clinical episode of herpes and warts, primary and secondary syphilis, gonorrhoea, chlamydia and non-specific urethritis.

<sup>(3)</sup> A narrow definition of new STI includes only bacterial STI diagnosed at the clinic, including primary and secondary syphilis, chlamydia and gonorrhoea.

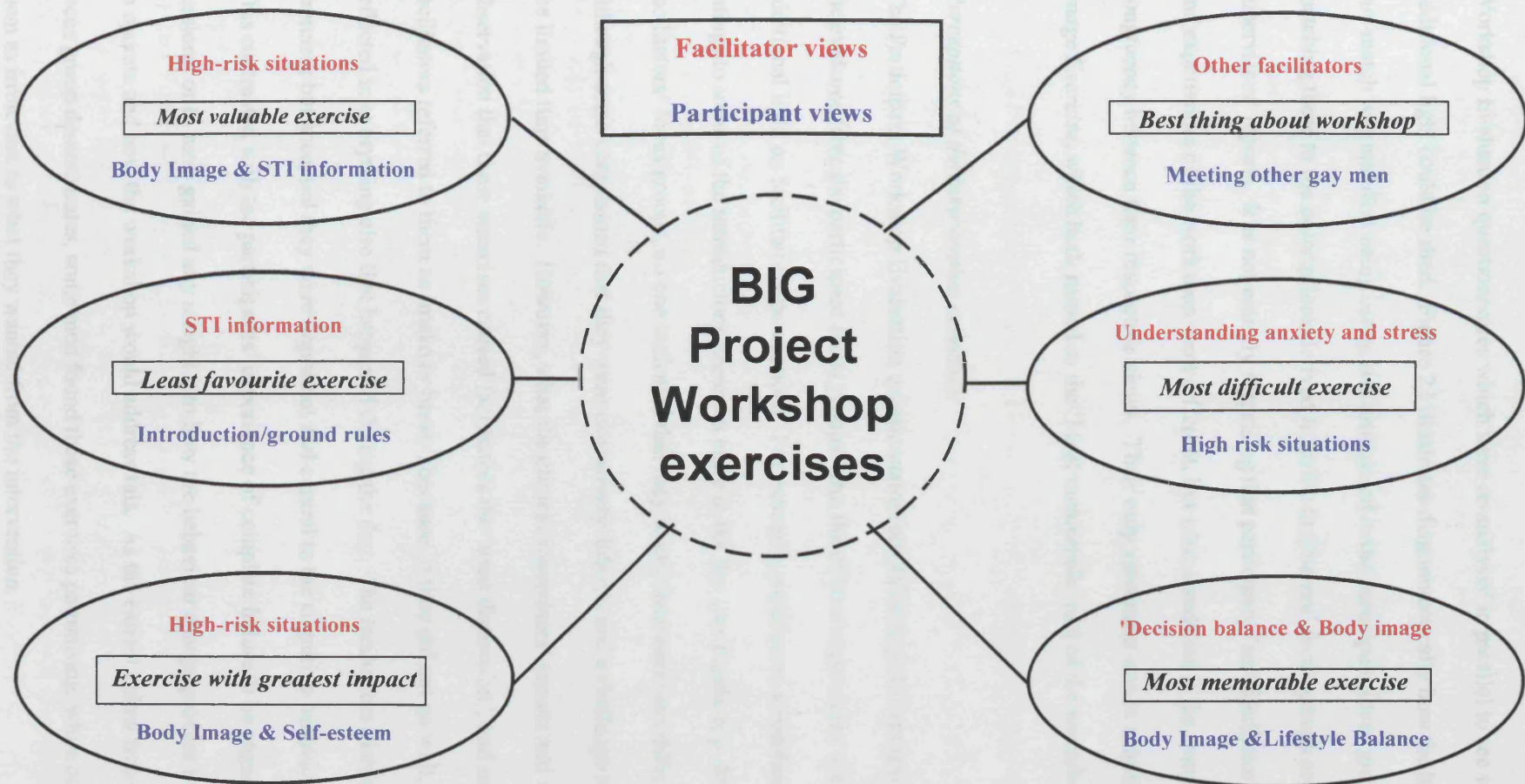
#### **8.4 Hypothesis 4 – Mis-matched expectations and perceptions**

In the process of analysing facilitator and intervention participant focus group transcripts it became clear that there was a mis-match between the two groups' respective experience of the BIG Project Workshop. This mis-match was most obvious in how they described individual workshop exercises, for example which exercise was the most difficult; which one had the greatest impact; which one was the most useful, etc. In contrast to the second hypothesis, described above, which questioned the intervention's theoretical underpinnings and its actual content, the idea being investigated here is that discrepancies between facilitators' and participants' ideas about the workshop, about what it should be like, how it should be delivered, etc. were manifest in what actually happened 'on the ground'. This in turn affected how facilitators delivered the intervention and what participants received. In short, this meant facilitators and participants failed to connect with one another in the workshops and that this somehow influenced the trial outcome.

The recent literature has made much of the importance of process and quality assurance evaluations in behavioural intervention trials (Bonell & Imrie 2001; Elford *et al.* 2002b; Kamb *et al.* 1996; O'Leary *et al.* 1997; Wight & Obassi 2003). Although these authors seem to emphasise the importance of ensuring an intervention is actually delivered as intended, process and quality assurance evaluations are also key to understanding what actually happens in a trial, and in this way help us to interpret the trial results. The approach adopted to do this in the BIG Project involved considering the experiences of those delivering and receiving an intervention together and separately (Metcalf *et al.* 2001; O'Leary *et al.* 1997; Padilla *et al.* 2001).

Participant and facilitator experiences were first considered separately and then parallel to each other to attempt to describe the actual manifestation of the hypothesised mis-match. The exploration was based mainly on the focus group transcripts and other qualitative data.

**Figure 22:** Diagrammatic presentation of the mis-match in participant and facilitator perceptions of BIG Project Workshop sessions



In the second part, analysis relied on the clinical supervisors' reports and the Participant Workshop Evaluation questionnaires which were re-analysed in parallel to see what additional light could be shed. Figure 22 illustrates diagrammatically how the hypothesised mis-match was manifest using categories articulated in the participant focus groups and matching these to the descriptions derived from the facilitators' focus groups and the clinical supervisors' reports. It is not entirely surprising that participants' and facilitators' perceptions and experiences of the workshop were different, but what stands out is the complete lack of congruency between their respective views. Their only agreement was in respect to the *Body Image Exercise*, which both named as the 'Most memorable' part of the workshop.

#### *Perceptions of the intervention exercises*

The Participant Workshop Evaluation questionnaire (see Table 8, p. 137) essentially mirrored the evidence from the participant focus groups. But the clinical supervisors' reports shed additional light on facilitators' perceptions. For example, participants consistently gave poor ratings to some of the introductory exercises early in the day (see Figure 6, p. 86). In the facilitators' focus groups, no one indicated that they found these exercises difficult to deliver, although some complained that they were excessively didactic and a challenge to complete in the limited time available. However, what the clinical supervisors' reports add is an observation that these exercises caused facilitators the 'most discomfort', and some facilitators referred to them as 'make or break', because, if they did not go well, it would be reflected in everything else that happened during the day. The facilitators disliked these exercises but accepted they were important and central to the cognitive-behavioural approach. This contrasted with the participants' experience of complete failure to be engaged by these sessions, or to have gained any insight into how the behaviour change process was theorised to operate and how the workshop would address this. As the extract below from a participant focus group demonstrates, some men found these exercises patronising, while others saw them as irrelevant to what they wanted from the intervention.

R3 'Well, basically, it was all sort of psycho-babble stuff coming at you at the beginning. And it made me feel as though 'Hey, I actually think I'm okay', and it was as though they were trying to make me believe that I have some sort of problem. It was almost there, that 'Now children you're not saying the right things here'. I don't know if any of you found it? I just found it was, it verged on patronising a couple of times.'

R2 'I didn't find that... But I agree with you about the business on the start where you have to sort of create the space, but then, you know, I accepted that as part of the rigmarole that they want you to go through ... It didn't make me feel any safer, and I guess I thought it was making the morning drag. It wasn't what I expected the workshop to be about, really. I found myself thinking that perhaps I should bolt at lunch.'

(FG#1 – Interventions)

Another example of the failed connection between participant and facilitator perceptions involved the two exercises consistently rated most highly by participants – the Safer Sex Experts and Body Image exercises. All the facilitators, without exception, indicated that these were their least favourite parts of the workshop. For example, in relation to the Safer Sex Experts, the clinical supervisors' report talks of facilitators claiming to 'be sick of the sound of my own voice' and 'disliking giving out information like a lecture', views that they also forcefully articulated in the focus groups.

R7 'It's supposed to work with them being the ones who answer their own questions, but that's really hard to control, so I tend to leave [co-facilitator] to try and keep it moving without it just becoming a quiz for me. Because, you know, well, I think that's just time wasted. They could get that from anyone in the clinic.'

(FG2 Facilitators)

According to the clinical supervisors' report, facilitators viewed delivering the Body Image exercise with 'trepidation' because participants 'either love it or hate it, and when they hate it, they blame it on us.' Although the facilitators acknowledged the exercise's popularity with the participants, they felt that it 'took much skill to run it successfully', and there was always potential for it to go wrong.

### *Summary*

Evidence from the focus groups, Participant Workshop Evaluation questionnaire and the clinical supervisors' report all point to a significant mis-match between facilitator and participant perceptions and expectations of what the intervention was supposed to be like 'in

action'. However, what cannot be measured specifically, either objectively or subjectively, is the extent to which the mis-match may have affected the trial outcome. As suggested in the case of the second hypothesis, the mis-match may be more indicative of inappropriate targeting and exercise content than failure on the part of the facilitators to deliver what was being asked of them. It may also be that the relatively structured, therapeutic delivery approach, developed to ensure consistency of delivery and to aid the facilitators, was not appropriate for the participants or in line with their expectations of what would happen in a one-day workshop. Given the intervention team's experience of previous process evaluations of the 'Changing personal sexual practice' intervention, it is somewhat surprising that these issues did not appear, or if they did were overlooked, in the earlier evaluations (Billington *et al.* 1997; Billington & Wanigaratne 2000; Wanigaratne *et al.* 1992; Wanigaratne *et al.* 1996; Wanigaratne *et al.* 1997; Williams *et al.* 1993).

### **8.5 Hypothesis 5 – Intervention as a socialisation vehicle**

A recently published Cochrane review of sexual risk behaviour interventions for HIV prevention in men who have sex with men asserted that the most likely explanation for the BIG Project results was that 'the intervention introduced men with a recent history of STI to potential partners who were themselves at increased risk of STI' (Johnson *et al.* 2003). The review goes on to propose two possible ways that this could have operated. The first is that 'the reduction in unprotected sex' associated with participants reported increased condom-use 'was overwhelmed by an increase in the prevalence of infections in the pool of partners' (Johnson *et al.* 2003). The second is that 'unprotected sex may have actually increased during the first weeks after the groups met (and behaviors were not being measured), followed by a wave of sexually transmitted infections which convinced participants to reduce risky behaviour' (Johnson *et al.* 2003). Neither of these proposed explanations is based on trial data and, in fact, both presuppose that the majority of men's sexual contacts came from within the study cohort. This seems highly unlikely given that the men only came together as

a group on a single occasion and that participants were drawn from geographically dispersed areas of London and beyond.

In contrast to Johnson *et al.*'s encapsulated single explanation of the trial results, the hypothesis that emerged from the process evaluation data was more measured – that being that the intervention brought together men and helped meet some of their social needs, and in the process brought like-thinking individuals together. This may, in turn, have allowed some participants attitudes and unsafe sexual practices to be re-enforced rather than challenged.

How this idea came to light has implications for design and outcome measurement of group interventions for sexual health promotion and HIV prevention. Because of its location in the West End, less than 25% of patients using the Mortimer Market Centre are resident in the local health authority catchment area (unpublished clinic data). The majority of users come from other areas across London and beyond. Similarly trial participants were drawn from a wide geographic area. In the course of the trial it became obvious that frequently men coming from either outlying suburbs or towns outside London stayed on after the workshops to socialise in the so-called gay village in Old Compton Street, Soho. What was surprising, however, was that frequently men who first met at the workshops went off to Soho to socialise together. Facilitators observed this firsthand on several occasions.

On a separate occasion, one of the clinic nurses recounted to the BIG Project Study Group how he had seen two men he had previously referred to the study attending the clinic together. It emerged that after meeting in the workshop, they had gone to socialise in Soho and, with time they eventually become involved with each other and had ended up becoming boyfriends. On the occasion they were attending the clinic together, they had decided to both test for HIV as part of formalising their relationship.



What brought this issue to light again was a participant attending for a focus group who recounted how he had become friends with two men from the workshop, who had become boyfriends after meeting through the BIG Project. Both men had received invitations to the focus group but declined to attend because they felt the researchers would disapprove of them becoming partners as a result of meeting through the BIG Project – a further example of participant misperceptions of the aims and objectives of the workshop.

The possibility that the workshops provided a place where social contacts were made, was entirely unforeseen in the design stage of the evaluation. And equally no consideration was given to the possibility of meeting sexual partners through the workshop, or that it might re-enforce rather than challenge, participants' attitudes and sexual risk behaviours.

Consequently, there was no specific attempt to measure any of these eventualities. With the benefit of hindsight, this was perhaps an obvious possibility. But in reviewing the behavioural intervention literature, it appears that it is something that has been overlooked by nearly all researchers conducting behavioural group intervention trials. Even in the case of interventions that explicitly aimed to provide a social environment to bring 'like-minded' gay men together, there was no consideration given to the possibility that group interventions might serve to re-enforce sexual risk behaviours among a group of men with similar behavioural repertoires. Rather, it seems to have been assumed that the peer effects in group-situations are always positive. Several studies deemed methodologically sound by Oakley *et al.* explicitly aimed to promote dialogue between gay men about safer sex issues in either group or peer-education settings (Oakley *et al.* 1996). But to date no methodologically rigorous evaluation studies have reported the possibility of an unintended effect on any groups, nor have they even indicated that they attempted to take account of this possibility (Choi *et al.* 1996; Kegeles *et al.* 1996; Kegeles *et al.* 1999; Kelly *et al.* 1997; Peterson *et al.* 1996; Peterson & DiClemente 1994; Robert & Rosser 1990; Rosser *et al.* 2002; Tudiver 1992; Valdiserri 1989).

How this phenomenon might have ultimately influenced the trial results is not entirely clear. It would seem that Johnson *et al.*'s interpretation is somehow too simple, overly ambitious and somewhat mechanical (Johnson *et al.* 2003). If the focus group participant's account can be considered accurate, it would seem the most likely effect of men meeting through the workshops was that some went on to become regular male partners, and some are likely to have had casual sexual relationships with men they met in the group. In turn, this may have contributed to some biased or less than entirely accurate reporting of behaviour in follow up questionnaires, but the scale and extent is impossible to estimate. This is just supposition. Rather than explaining the trial outcomes, the important lesson from this hypothesis is what it highlights about possible unintended effects of group interventions and the need for these to be considered by evaluators.

#### **8.6 Hypothesis 6 – Risk compensation**

Each of the hypotheses examined so far in some way presupposed a deficiency in one or more aspects of the design and conduct of the trial, or a deficiency in the content and delivery of the intervention. It would be imprudent, however, not to give equal consideration to the possibility that there was nothing wrong with the trial or the intervention and the results are what should have been expected. If this were the case, how could the results be explained?

One possible explanation is that the intervention in some way provided participants with increased self-confidence to negotiate consistent condom-use, but because they had more anal sex partners, they were more likely to experience more condom failure, or to engage in sex with partners already infected with an STI. This proposition is partially supported by the cumulative results of the psychometric data, and specifically the Situational Self-confidence questionnaire (see Table 14, p.164 and Table 17, p. 176). However, if this explanation proved correct it would be without precedent in the existing published literature (Ellis *et al.*

2003; Johnson *et al.* 2003; Oakley *et al.* 1996). Nevertheless, there is a theoretical explanation that could support this possibility.

#### *Risk homeostasis and risk compensation theory*

Risk compensation theory posits that people are willing, and in fact expect, to live with a certain level of health risk and attempt to balance the rewards of risk-taking against the perceived negative consequences (Adams 1995; Richens *et al.* 2000; Wilde 2001).

According to the theory, when safety devices or other risk reduction strategies are adopted, such as automobile seat belts, the safety benefits are partially offset by compensatory behaviour. For example, driving at increased speed, increases the risk (risk compensation) such that overall individual level of personal risk returns to its previous level (risk homeostasis) (Adams 1995; Pinkerton 2001; Richens *et al.* 2003; Wilde 2001). Over the past ten years, risk compensation theory and the concept of risk homeostasis have engendered considerable discussion, particularly in the context of road safety. Risk compensation has been proposed as an explanation for the failure of mandatory seat belt legislation to deliver commensurate reductions in the number of road traffic deaths in most Western countries (Adams 1994; Harvey & Durbin 1986; Organisation of Economic Co-Operation and Development 1990; Richens *et al.* 2000; Wilde 2002).

The majority of published research on risk compensation and risk homeostasis is in the field of road traffic and vehicle safety (Assum *et al.* 1999; Sagberg *et al.* 1997). But the ideas have been advanced in other areas as diverse as gambling, prevention of computer viruses and sexual health (Pinkerton 2001; Richens *et al.* 2000). Most recently, marketing researchers have investigated risk compensation in relation to a class of products they refer to as 'consumer remedies', for example nicotine replacement products and debt consolidation services, which offer solutions to consumer problems (Bolton *et al.* 2003).

### *Risk compensation and sexual health*

In the field of sexual health and HIV, several papers have suggested that sexual behaviour may be subject risk to compensation and risk homeostatic influences (Aral & Peterman 1996; Pinkerton 2001; Richens *et al.* 2000; Tankersley 1996). Although the first papers mainly considered whether risk compensation was a factor explaining why increased self-reported condom-use had not led to reduced STI transmission (Zenilman *et al.* 1995). The focus of more recent work has been on the relevance of risk compensation as a factor explaining sexual behaviour changes among gay men since the widespread introduction of HIV antiretroviral therapies and the availability of post-exposure prophylaxis for sexual exposure to HIV (Elford *et al.* 2000a; Elford *et al.* 2001; Geile *et al.* 2002; Kelly *et al.* 1998a; Kelly & Kalichman 1998; Pinkerton 2001; Rosengarten *et al.* 2000).

### *Can risk compensation theory explain the trial results?*

Interpreting the BIG Project trial results from a risk compensation perspective presumes that intervention men increased their condom-use and condom negotiating skills in different situations, making them feel more 'safe' in relation to the risk of HIV infection. At the same time, they compensated for this by having more sexual contacts, and by engaging in more acts of AI with more partners than they had in the past, that is, than they reported at baseline. Rather than reducing the risk of acquiring an STI through more consistent condom-use, the combined effect of more partners, more acts of AI and increased likelihood of condom failure associated with more acts of anal sex, negated these benefits such that their actual risk increased overall (Richens *et al.* 2000).

There are several strands of evidence from the trial that would appear to support the risk compensation hypothesis. Firstly, there is consistent evidence that overall, self-reported condom-use increased and by all measures it was greater in the intervention group (see Tables 14, 15 and 16). The proportion of the intervention group that reported all episodes of AI in

the last month were condom protected increased, from 48.8% (60/123) at baseline to 63.3% (50/79) at 12 months follow up (see Table 14, p. 162). Two of the psychometric scales (Situational Self-confidence and the Communications & Safer Sex Efficacy sub-scales of the HIV Attitudes questionnaire) indicated there were improvements in condom negotiation and condom-use self-efficacy in the intervention group (see Table 14, pp.165–166). Taken together these self-reported measures provide some evidence that condom-use and condom-use skills among intervention participants improved, and that the first part of the risk compensation proposition cannot be immediately refuted.

On the other hand, the evidence to support the second part – behavioural compensation – is less convincing. Men in the intervention arm did report more sexual contacts in the last year at 12 month follow up compared to baseline (baseline = 20 [range 1–300] vs. 12 months = 23 [1–299]). They also reported more anal intercourse partners over the same time period (baseline = 3 [range 1–100] vs. 12 months = 6 (0–60)) and in both cases these were greater than among the controls, although not statistically significant. However, the participant questionnaires did not include any measures of the total number of AI episodes in any given time period, the number of episodes with new partners or the rate of condom failure. These are essential data inputs if any estimate of the effect of risk compensation is to be undertaken (Pinkerton 2001).

Risk compensation advocates argue that the most important indicator of risk compensation in practice is increased new partner acquisition, particularly in high-risk populations such as gay men (Pinkerton 2001; Richens *et al.* 2000). However, to estimate the effect of risk compensation on STI or HIV incidence, it is change in the number of acts of intercourse and the proportion of acts that are condom protected – where there is no condom failure – that is more important (Pinkerton 2001; Richens *et al.* 2000). Using mathematical models, attempts

have been made to estimate the effect of risk compensation in relation to sexual behaviour and specifically condom-use (Pinkerton 2001; Richens *et al.* 2000). The most sophisticated of these models requires data from baseline and each follow up survey on total number of acts of intercourse and the proportion of acts that were condom protected, as well as the actual number of 'new' sexual partners (Pinkerton 2001). But unfortunately in most research studies these data are not collected either systematically or with sufficient accuracy to make modelling possible because most have to rely on an assumed or consistent condom failure rate. As research cited earlier in this thesis indicates, condom failure rates are subject to different influences and variation in condom failure with different partners is common (Golombok *et al.* 2001). The required behavioural data to undertake any type of modelling was not collected in the BIG Project and, sadly, it is therefore impossible to model any risk compensation effect in the trial.

#### *Against the risk compensation argument*

Although an intuitively attractive explanation for the trial outcome, the risk compensation proposal does not hold up very well under closer scrutiny using the other trial data. Firstly, even acknowledging its relative insensitivity, there was no change in the median number ( $n = 1$ ) of UAI partners between baseline and 12 month follow up, either comparing between arms or within arms separately (see Table 14, p. 163 and Table 15, p. 170). Secondly, significantly more intervention men knew the HIV status of their last UAI partner to be the same as their own at 12 month follow up compared to baseline, and compared to the controls (see Table 14, p. 163). Thirdly, the significant difference in STI diagnosis rates observed was in respect to 'any new STI', and not just bacterial STI, which would be a better proxy of recent high-risk sexual behaviour (Aral & Peterman 1998; Singaratnam *et al.* 1991; Young *et al.* 1991; Zenilman *et al.* 1995). If risk compensating behaviours were generalised in the intervention group, it would be expected that bacterial STI rates would also have been significantly higher given the likely inclusion of some latent infections in the first definition.

Fourthly, the ‘on treatment’ analysis of the STI data showed that the increased STI diagnoses were not restricted to men who attended the workshop but were in fact generalised among all men in the intervention arm. In a situation where the risk compensation explanation held, this negative effect should have been more pronounced in those who completed the intervention – the ‘on treatment’ group. Finally, as shown earlier in this chapter, for the intervention group, acquisition of a new regular partner appeared to reduce the risk of having an STI diagnosed compared to the controls (see Table 22). For the risk compensation explanation to hold the opposite would have been expected.

### *Summary*

Only the risk compensation hypothesis did not in some way presume a deficiency in one or more aspects of the trial. According to a risk compensation interpretation, the self-reported increased condom-use and increased proportions of men with an STI diagnosed were in no way incongruous. Rather the increase in condom-use was real, but the benefits were offset by increased partner change and more episodes of AI, which led to increased risk of STI.

Several strands of evidence appear to support the risk compensation explanation, for example the increase in self-reported condom-use and the increase in both the number of sexual contacts and AI partners. However, key data needed to model its effects are unavailable. At the same time, several other factors appear to run counter to the risk compensation argument and as such it seems unlikely that the risk compensation hypothesis can fully account for the trial results.

## **8.7 Conclusions**

This chapter examined six hypotheses in an effort to explain the trial results more comprehensively. Five of the hypotheses presumed the trial results were a consequence of some deficiency in the trial design or the conduct and delivery of the intervention. Three hypotheses seem to add most to our understanding of why the intervention failed to deliver as

anticipated. First, the trial follow up and retention procedures seem likely to have contributed to an unintended intervention effect among the controls that influenced their reported behaviours at the two follow up points. Second, there seems to be relatively strong evidence that the models used to develop the intervention and the assumptions made in targeting the intervention content were wrong for the group of men recruited to the trial. And third, there was a mis-match in facilitator's and participants' expectations and perceptions that was manifest in the way the intervention was delivered and received. As a consequence the intervention failed to meet the participants' actual prevention needs and did not challenge assumptions about their behaviour or support them appropriately in making behavioural change. In the case of the other three hypotheses, the trial data either refute them entirely, for example in the case of new regular partnerships, or are inadequate to draw any kind of conclusion, as in the case of the workshops' serving as a socialisation vehicle introducing men to new partners.

Although unable to identify a single explanation for the trial outcome, what is perhaps most valuable about these additional analyses is what they tell us about the complexities of RCTs of behavioural interventions for STI and HIV prevention. In the process of examining each hypothesis, key methodological issues have arisen that have so far been overlooked in designing rigorous evaluations and the measuring of complex behaviours. The first hypothesis highlighted the need to take account of the research effect on participants who serve as consenting controls and with whom investigators need to maintain contact over time. In the context of individually randomised, brief, one-off or limited-session interventions, intensive retention and follow up procedures are essential, but they may constitute a more powerful and ongoing influence on control participants than the actual intervention does on those who receive it. Similarly the fifth hypothesis – that the intervention may have served as a socialising vehicle – while not well supported by the data from this trial, is something that has been almost completely overlooked by researchers. In these complex trials, researchers



need to look beyond the obvious when considering possible sources of any unintended intervention effects.

The second and fourth hypotheses each draw into question the role of theory and how it influences the content and delivery of interventions. Analysing the data in respect to these two hypotheses elicited important information about how theory and models of behaviour change can be best used in developing interventions. They demonstrated a frequently neglected precaution about using theory, that being that theories used to design interventions need to be relevant and understandable to the intended intervention recipients as much as with the investigators (Catania *et al.* 1990; Ramos *et al.* 1995; Shain *et al.* 1999). Single theories that seem appropriate to a team of investigators may not have the same appeal or resonance with the intended target audience, or with those who will deliver the intervention, and this needs to be established at the outset (Elford 2004; Elford *et al.* 2002a; Hart 2004; Hart 1996; Hart 1998; Hart & Elford 2003). Intervention purists may implore prevention researchers to be cautious in their eclectic use of theory and models of behaviour change but, if as seems to be the case in the BIG Project, the intervention was excessively therapeutic in its approach, or it failed to account of the self-identified needs of the target audience, it may not be well received and, may be exceedingly difficult to deliver (Koblin *et al.* 2003) (Personal communication: Dr Connie Celum, Department of Epidemiology, School of Public Health and Community Medicine, University of Washington, August 2001).

Several of the hypotheses highlight the value of formative research and process evaluation both before the main trial is undertaken and during the main trial itself. In the past, formative and process evaluations have tended to been seen as 'bolt-ons' and added luxuries (Stephenson & Imrie 1998). As this trial and other recently published studies have demonstrated, initial formative evaluation needs to be revisited throughout the trial to ensure that an intervention evolves and continues to take account of changes in the target audience

(Elford *et al.* 2002b; Elford *et al.* 2001; Flowers *et al.* 1999; Flowers *et al.* 2000b; Hart & Elford 2003; Ramos *et al.* 1995; Shain *et al.* 1999; Stephenson & Imrie 1998). Process evaluation was until recently largely overlooked by many behavioural intervention trialists, the majority of whom were schooled in clinical or drug trials where process and explanatory pathways are less important. However, as this trial and other examples of interventions that failed to deliver demonstrate, process evaluation is invaluable in explaining trial results (Elford 2004; Elford *et al.* 2002b; Hart 2004; Hart *et al.* 2003; Wight & Obassi 2003). It does this by providing insights into whether and how the trial and the intervention are 'working'. However, to be genuinely useful, process data needs to be available during the actual intervention and, importantly, during the follow up and while the main outcome analysis is being undertaken. In this way it can contribute to key decisions that should guide analysis and the interpretation of the results. Regrettably, restricted resources precluded a full and comprehensive process evaluation being undertaken in the BIG Project and from analysis being undertaken while the intervention was actually in the field. But the limited process data available are illuminating and provide several key explanations to help understand the trial results.

The third hypothesis concerning new partnership formation underscores investigators' need to be open to incorporation of other research results into their analysis, and not simply to accept them, or accept that they apply to every sample. The robustness of the data used in this analysis were less than optimal. Nevertheless, the result that for intervention men acquiring a new regular partner appeared to be protective in respect to new STI diagnoses highlights another unanticipated outcome, which ran counter to both the current literature and the investigators' intuition.

Finally, the risk compensation hypothesis highlights two further points. Firstly, that unanticipated overall results may not necessarily indicate that something went 'wrong', but

that there may be an alternative interpretation that is equally valid. And secondly, that the wider behavioural literature and its critique may have considerable relevance to our understandings of HIV and STI prevention. Researchers have only begun to tap into the behaviour theories and explanations from other disciplines. The success of Kelly *et al.* in developing peer-delivered HIV prevention interventions based on sociological theories relating to agricultural innovation illustrates the potential to draw from theory in other areas (Rogers 1983). Although other research using this model has subsequently shown that it may not always be readily transferable, Kelly *et al.*'s work nevertheless highlights the value of prevention research widening its theoretical perspectives (Elford 2004; Hart 2004; Hart Elford 2003; Kelly *et al.* 1997; Pinkerton 2001; Rogers 2000).

## **Chapter 9**

### **Conclusions – The impact on research and practice**

#### **9.0 Introduction**

Naturally, it was somewhat disappointing that BIG Project Workshops failed to deliver as originally hypothesised. This had a major impact on the trial's demonstration value among prevention funders and prevention providers, many of who chose to ignore the results because they neither fully supported, nor categorically reject, current practice. However, among the research community the 'negative' findings have generated considerable interest, and the BIG Project has probably come under closer scrutiny than had it been successful in reducing STI (Bonell 2002; Bonell *et al.* 2003; Bonell & Imrie 2001; Holmes 2001; Johnson *et al.* 2003; Ross & Wight 2003; Stephenson *et al.* 2000; Stephenson *et al.* 2003). This concluding chapter considers the impact of the trial results on local prevention policy and practice and on directions for further research.

## **9.1 Impact on local HIV prevention policy and practice**

Over the course of the trial, the BIG Project generated considerable interest and discussion among local HIV prevention funders and gay men's prevention providers, who were anxious to know the outcome. In addition to this dissertation, the BIG Project also provided a research focus for another PhD examining the politics of the research-policy interface in relation to commissioning of HIV prevention (Bonell 1999; Bonell 2002). However, despite early enthusiasm, the main trial results have had little impact on decisions and planning of HIV prevention policy or practice and there are several possible explanations for this.

Based on the trial results, the recommendation to the clinic was that the BIG Project Workshop interventions not be implemented and that continued provision of 'Getting the sex you want', successor to 'Changing personal sexual practice', should be reassessed based on more comprehensive outcome evaluation. The aims of the recommended evaluation would be to assess potential negative effects of the intervention in relation to sexual risk behaviour and STI/HIV among attendees, and to determine whether it continued to offer a good investment of prevention resources based on more robust outcome measures. However, this did not happen and, as noted in Chapter 3, 'Getting the sex you want' continued to be offered, in an almost entirely unaltered form for a further two years, until June 2000, when it was finally dropped because it failed to attract sufficient numbers (Personal communications: Mark Maguire, HIV and Sexual Health Manager, and Simon Paragreen, GUM Health Promotion Coordinator, Camden & Islington Health Promotion Services, October 2001).

Local prevention commissioners and practitioners, initially eager to see the results of the BIG Project, have proved equally unresponsive to the trial's main recommendations. While it is not entirely surprising that local prevention practice has not changed fundamentally on the strength of a single trial, it is somewhat disheartening that there has been no action on the main recommendation, that group work and other intensive face-to-face interventions should

be reviewed regularly to ensure that they continue to offer effective and good value prevention. The importance of this recommendation has been acknowledged by commissioners, but to date there has been no action at the commissioning level (Huxter 2003). For their part, HIV prevention practitioners have almost completely dismissed this recommendation, claiming that the trial intervention was not representative of current community-based work and therefore the findings are not relevant to local practice (Personal communications: Tim Foskett, Project Officer and Health Psychologist, PACE Counselling Services, and Martin Dockrell, Chair, Gay Men Fighting AIDS, February 2001). Despite the evidence from this trial and evidence from UK evaluations that raise important questions about the effectiveness of group and intensive face-to-face prevention activities, these interventions continue to account for the largest single budgetary item in gay men's HIV prevention in Greater London for the contract period 2001–2007, and there is no explicit agenda to see any of them rigorously evaluated (Devlin *et al.* 2003; Hartley *et al.* 1999; Hickson & Weatherburn 2001; London Gay Men's HIV Prevention Partnership (LGMHPP) 2003). In fact, as one of the outgoing HIV service commissioners observed, 'It is remarkable that a trial of local prevention provision has had so little impact on local decision-making or planning.'

How can such a minimal impact on both local policy and practice be explained? One key obstacle to influencing local community policy has been the continually changing context of HIV prevention provision. As described in Chapter 2, at the time the trial was originally set up, providers and commissioners were wrestling with a new system of outcome based commissioning and annually renewable contracts. Since then there has been a wholesale reform of gay men's HIV prevention purchasing and provision in London, with a total reconfiguration of services and changes in key personnel (Anderson *et al.* 1994; Keogh *et al.* 1997; The Strategy Development Group of the Community HIV and AIDS Prevention Strategy (CHAPS) 1998). However, even as these reforms have started to settle in and

become part of the policy and practice context, there has been little interest in looking at the effectiveness of local prevention practice using the most rigorous methodologies (Bonnell 2002; Devlin *et al.* 2003; Ellis *et al.* 2003).

A second potential explanation was the limited involvement of local commissioning, voluntary sector and other provider stakeholders in the BIG Project Study Group and in the trial itself. Membership of the Project Study Group (see Appendix 10) was restricted to researchers and frontline GUM clinical staff without direct involvement of either local community prevention providers or local community members. As a consequence, much of the demonstration value was lost. There was also no opportunity for those best placed to influence the evaluation agenda in the community to contribute to or learn from the trial. Ensuring that key stakeholders and the community are involved throughout the intervention development and implementation, and especially the design and conduct of the evaluation, is an important lesson of this trial.

Thirdly, there has been an undeniable sea change in views about HIV prevention since the widespread introduction of effective antiretroviral therapy. Many activists have argued that that the urgency has gone out of prevention (Rotello 1998) and a sense of prevention fatigue has been almost palpable among both gay men and HIV prevention providers. While on the one hand, this partially explains the failure of this study to influence local decision-making, on the other, it highlights central challenges for HIV prevention and sexual health promotion in the future.

Fourthly, failing to significantly influence local HIV prevention policy and practice is not unique to this trial (Bonell 1999; Bonell *et al.* 2003; Ellis *et al.* 2003; Hart & Elford 2003; Kelly *et al.* 2000b; Oakley *et al.* 1996; Peersman *et al.* 1999). Obstacles to improving the 'research into practice' translation process have been the subject of considerable discussion

and even research studies, including controlled trials that aim to demonstrate the institutional success of organisations that adopt more evidence-based approaches (Adams *et al.* 2000; Bonell 2002; DiFranceisco *et al.* 1999; Imrie *et al.* 2000; Kelly *et al.* 2000a; King 1997; Neumann & Sogolow 2000). Regrettably nearly all published work has been done in the United States, where federal government agencies and budget policies have a greater capacity to influence local policy and practice (Kelly *et al.* 1998b; Neumann & Sogolow 2000). In the UK the only explicit commitment to improving the evidence base and evidence-based practice in sexual health and HIV is contained in the *National Strategy for Sexual Health and HIV* and is being implemented by the Health Development Agency for England (DoH 2001; Ellis *et al.* 2003). However, operational, management and social research into the barriers to more evidence based HIV prevention practise are also needed, not just the policy commitment. Without appropriate incentives or explicit direction, there is unlikely to be any genuine local commitment to improving the rigour of local prevention intervention evaluation.

## **9.2 Directions for future research**

It is perhaps because the intervention failed to demonstrate a positive prevention effect that the BIG Project's most valuable contribution to date has been in advancing the methodological research agenda in this field of sexual health and HIV prevention (Holmes 2001; Johnson *et al.* 2003; Peersman *et al.* 1999; Sogolow & Peersman 1998). In particular, four areas stand out as warranting significant new research initiatives: 1) development of RCT methodology in the context of sexual health and HIV; 2) outcome measures; 3) intervention development and theory, and 4) formative and process evaluations and their contribution to successful interventions and instructive experimental evaluations.



### *Development of RCTs in sexual health and HIV prevention*

The BIG Project's most important contribution has been to confirm the importance and need for sexual health, HIV prevention and other health promotion interventions to be as rigorously evaluated as other health interventions (Bonell *et al.* 2003; Holmes 2001; Oakley *et al.* 1996; Ross & Wight 2003; Stephenson & Imrie 1998). This means more randomised trials, and these are undoubtedly warranted (Health Protection Agency 2003). The consequences of HIV/AIDS, STI and unintended pregnancy are extremely important to health. However, as has been argued, for different reasons elsewhere in the literature, randomised trials are most often a complex, resource-intensive, and time-consuming method for evaluating urgently needed interventions and often the practical constraints of a situation make an experimental evaluation extremely difficult (Bonell *et al.* 2003; Kippax 2003; Stephenson & Imrie 1998). But this should not be interpreted as an excuse to avoid rigorous evaluations. There is an urgent need to consider whether there are pragmatic ways of undertaking trials that can produce high quality effectiveness evidence in circumstances that most approximate real life, while at the same time producing the required explanatory evidence needed to advance understanding of the influences on sexual behaviour change.

There are also several other methodological questions that should be addressed. For example, the impact of trial procedures, follow up and retention, which as this study and Project RESPECT suggest, may have important effects on control participants, equal to or in excess of that of a single session, or otherwise brief intervention (Kamb *et al.* 1998). In some recent trials there has been a move away from structured follow up procedures, relying instead exclusively on objectively measured biological endpoints (Personal communications: Dr Tom Peterman, STD/HIV and TB Prevention Research Branch, Centers for Disease Control, Atlanta GA, USA, September 2001). This approach gives clear answers to research and policy questions about interventions' effectiveness, but they have no value in terms of explaining how or whether an intervention works as intended, or if it actually changes

behaviour. These sort of explanatory data are still urgently needed and must be fed into the development of the next generations of behavioural interventions.

### *Choice of outcomes*

As the first randomised trial of a behavioural intervention specifically focusing on gay men to include biological measures as the primary trial endpoint, this study highlighted the importance of choice of outcomes in determining an intervention's effectiveness. Since the BIG Project's instigation there has been considerable discussion about the importance of choice of outcomes in trials of sexual health and HIV prevention interventions (Aral & Peterman 1996; Aral & Peterman 1998; Cowan & Plummer 2003; Fishbein & Jarvis 2000; Peterman *et al.* 2000a; Shain *et al.* 1999; Shain *et al.* 2003). Because the primary endpoint that determines the success or failure of a trial depends mainly on the behaviours the intervention aims to change, and the context in which the intervention is delivered, the choice of appropriate outcomes is often complicated by factors outside the trial (Cowan & Plummer 2003). However, there is now wide agreement among trial enthusiasts that in individually randomised behavioural intervention trials, objectively measured biological or disease endpoints provide the most persuasive evidence of effectiveness (Bonell *et al.* 2003; Cowan & Plummer 2003; Grosskurth *et al.* 1995; Hayes *et al.* 1995; Johnson *et al.* 2003; Kamb *et al.* 1998a; Kamb *et al.* 2000; National Institutes of Health 1997; Ross & Wight 2003; Stephenson *et al.* 2000). But the link between behaviours and biological endpoints is rarely straightforward. For example, the failure to satisfactorily explain the discordance between the STI diagnosis endpoints and the self-reported behaviour in this trial is not unique, but has also been found in intervention trials with an overall positive outcome (Kamb *et al.* 1998a; Kamb *et al.* 2000; Peterman *et al.* 2000b; Stephenson *et al.* 2000). Although studied extensively, the link between sexual behaviour and incident STI and HIV in many high-risk populations remains relatively poorly understood (Fishbein & Jarvis 2000; Peterman *et al.* 2000b; Shain *et al.* 1999; Shain *et al.* 2003). While the decision whether a behavioural

intervention is successful and worthy of general implementation may be based on a single, most likely, objectively measured biological outcome, there should be some hesitation in giving a wholehearted endorsement to the intervention, if the link between behavioural and biological endpoints cannot be established (Shain *et al.* 2003). Limited research in this area suggests that these links may often be associated with complex behaviours or interactions between behaviours and partner type, and there is a need for more research to understand this complex dynamic (Shain *et al.* 2003). Increasing our understanding of the relationship between such complex behaviours and incident STI or HIV may be easier and faster using case-control or re-infection studies than large-scale randomised trials.

### *Intervention development*

As discussed in Chapter 4, the BIG Project Workshop intervention had been in development for more than five years before the start of the trial, and it was more than eight years old when the final results became available and nearly eleven before they were published (Imrie *et al.* 2001). This may be somewhat longer than the case for other interventions, but it is still well within the range of normal (Kegeles & Hart 1998; Kegeles *et al.* 1999; Kelly *et al.* 1990; Kelly *et al.* 1997; Ramos *et al.* 1995; Rosser *et al.* 2002; Rosser *et al.* 1993; Shain *et al.* 1999).

Recently researchers have begun to argue that more time be spent on the formative research stages of an intervention's development and for the inclusion of development stages analogous with Phase I and Phase II developments in clinical trials (Campbell *et al.* 2000; Medical Research Council 2000; Nazareth 2003; Ramos *et al.* 1995; Shain *et al.* 1999; Stephenson & Imrie 1998; Stephenson *et al.* 2000; Sutton 2003). This is certainly appropriate to avoid either evaluating poor quality interventions or, worse still, implementing harmful ones. But it may add to the development time such that by the time an intervention has been shown to be effective it is no longer relevant to the target population (Elford & Hart 2003).

Appeals from some quarters to make more and better use of theory, and to adopt a wider theoretical perspective when designing interventions is laudable and certainly warranted (Albarracin *et al.* 2000; Fishbein 2000; Rogers 2000; Sutton 1998; Sutton 2003). But the empirical base for many potential theories is poor, and the lack of validation studies for new theories and models in the context of sexual health and HIV will add another stage and more time to an intervention's development (Campbell *et al.* 2000; Nazareth 2003; Ramos *et al.* 1995; Shain *et al.* 1999; Stephenson & Imrie 1998; Stephenson *et al.* 2000; Sutton 2003; UK Medical Research Council 2000). This is not to say that these stages are unnecessary or that they can be overlooked. On the contrary, to increase the likelihood of interventions being successful and effective we need to follow as closely as possible the pathways that are most likely to work. But we must also be mindful that many of the interventions evaluated and shown to be effective in the 1990s are almost undoubtedly fast approaching their 'sell by' date (Choi *et al.* 1996; Coates *et al.* 1989b; Elford & Hart 2003; Honnen & Kleinke 1990; Kelly *et al.* 1992; Rosser *et al.* 1993; Tudiver *et al.* 1992; Valdiserri *et al.* 1989). With the changes in the HIV epidemic, treatment and care since their evaluation, there must be serious questions about whether the effectiveness of these interventions can still be taken for granted (Devlin *et al.* 2003; Elford & Hart 2003; Ellis *et al.* 2003; Imrie 2003; Imrie & Johnson 2001). As a consequence, intervention development must clearly be another priority area for research. Research into new methods of intervention development might consider whether phased development and piloting of an intervention's content can be undertaken more expeditiously when done alongside aspects of formative research in separate but parallel studies.

### *Formative and process evaluations*

Recent successful, and less successful, intervention trials have demonstrated the value of good formative and process evaluations. These can no longer be seen as 'bolt-ons' or extras, but are a central part of a full-scale experimental evaluation (Elford *et al.* 2002b; Hart &

Elford 2002; Wight & Obassi 2003). But what remains open to debate is how to conduct them, how much to undertake, when, and using what methods. These questions can only be addressed by undertaking more process and formative research in the context of large trials and learning from these experiences. There is a counter argument, that these additional components of an experimental evaluation add to the time and the resources required and are unlikely to influence bottomline policy decisions. Therefore, an enquiry looking at what questions and which methods can most effectively and efficiently guide process and formative research programmes represents a good investment now, for the longer term.

### **9.3 Conclusions**

The primary aim of this dissertation was to describe the development, conduct and results of the RCT of the BIG Project Workshop intervention. A secondary aim was to describe the background context of the trial, specifically the limited evidence base for the effectiveness of HIV prevention targeting UK gay men and to consider the impact of the trial on local HIV prevention planning and provision and the wider research agenda. The intervention failed to deliver the prevention dividends originally hoped for and the trial results have proved less influential on local policy and practice than might have been expected. But the trial has succeeded in reminding us of the most important reason why sexual health and HIV prevention interventions should be rigorously evaluated – to avoid implementing costly, ineffective and, in this case, potentially harmful interventions. Scientific approaches to evaluation in health promotion are still in their relative infancy and this study is an important contribution. But it is still only a single step in terms of the longer-term developments necessary to effectively reduce HIV and STI incidence in an important at-risk population, and to ensure health promotion interventions are subjected to the same degree of rigour as other medical interventions.

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